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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

- FULL SCOPE -

TO

FRANCE

Paris, France

6 to 17 November 2006

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE

IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither

an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- a balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than eighty Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

REPORT

INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

-FULL SCOPE-

REPORT TO
THE GOVERNMENT OF FRANCE

Paris, France
6 to 17 November 2006

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Paris, France
6 to 17 November 2006

Mission date: 6 to 17 November 2006

Regulatory body: ASN

Location: ASN Headquarters, Paris, France

Regulated facilities and practices: Nuclear power plants, research reactors, fuel cycle facilities, medical practices, industrial and research applications, waste facilities, decommissioning and remediation, communication and public information.

Organized by: IAEA

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FOREWORD

by Mohamed ElBaradei
Director General

The General Conference Resolution of September 2006 related to the measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "Recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS."

At my opening speech of the fiftieth regular session of the General Conference in 2006, I stated that: "The Agency's safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators."

"A reduced scope IRRS was conducted for the United Kingdom Nuclear Installations inspectorate in March of this year. A full scope service will be conducted in France in November. The Agency has also received requests for IRRS missions from Australia, Canada, and Spain, and other Member States have expressed interest in having such missions in the near future. I would request all countries to take advantage of this service. I remain convinced that transparency and introspection are essential ingredients of an effective nuclear safety culture."

The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government authorities of France, an international team of twenty four experts visited the Autorité de Sûreté Nucléaire (ASN), the French regulatory authority for nuclear and radiation safety, in November 2006 to conduct the first full scope Integrated Regulatory Review Service (IRRS) mission.

The purpose of this IRRS mission was to facilitate regulatory improvements in France and throughout the world from the knowledge gained and experiences shared by ASN and the reviewers through the evaluation of the effectiveness of the French regulatory authority, its regulatory framework and its regulatory activities. The facilities and practices regulated by ASN include nuclear power plants, research reactors, fuel cycle facilities, medical practices, industrial and research activities, waste facilities, decommissioning, remediation and transport. In addition to the usual IRRS scope, ASN requested that this IRRS mission also cover ASN public information practices.

The IRRS Review Team consisted of experts from sixteen Member States (including several senior regulators) among them two observers, six staff from the IAEA and an IAEA administrative assistant.

The IRRS team carried out the review of the ASN in all relevant areas: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; emergency preparedness; radioactive waste management, the management system; transport (as a follow-up to an IAEA Transport Safety Appraisal Service – TranSAS); and public information and communication.

From an intensive series of interviews and discussions with key personnel at the ASN and other organizations, and the observation of a number of inspections across the whole spectrum of practices and activities, together with the documentation and self-assessment supplied by ASN in advance of the mission, the team presented its findings based on the IAEA safety standards. Additionally, the IRRS team, together with ASN staff, discussed policy issues relating to the regulation of nuclear and radiation safety. The results of the discussions will serve as a useful basis for the evolution of future IRRS missions and will assist with continuous improvement in the regulation of nuclear and radiation safety.

The IRRS Review Team noted the open, transparent and learning attitude of the ASN staff throughout this mission, and it was clearly evident that ASN had put significant effort into the preparation of the mission. During the review the administrative and logistical support was excellent and the team was extended full cooperation in technical discussions with ASN personnel.

The IRRS Review Team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to further strengthen the effectiveness of regulatory controls. These recommendations and suggestions are made to an organization that is seeking to improve its performance and many of them are related to areas in which ASN has already implemented a programme for change.

The IRRS Review Team considers it important to mention ASN's current efforts in ensuring greater consistency with the IAEA safety. Particular strengths of ASN, its regulatory framework and its regulatory activities identified by the team were:

- A mature and transparent nuclear regulatory system for basic nuclear installations (BNIs)
- A well-developed and comprehensive inspection programme including development of annual inspection programmes, preparation and conduct of inspections;

- Emergency exercises training involving BNIs;
- The use of independent expert advisory committees on a variety of topics and themes in the nuclear safety area and the systematic use of the technical support organization Institut de radioprotection et de sûreté nucléaire (IRSN);
- Internal training and an accreditation programme for ASN inspectors;
- Information and communications to the public;
- An active international role, particularly at the IAEA;
- A good regulatory framework for sustainable management of radioactive material and waste; and
- Good implementation of the 2004 TranSAS mission recommendations and suggestions.

The report includes recommendations or suggestions where improvements are necessary or desirable to further enhance the legal and governmental infrastructure for nuclear and radiation safety.

During the course of the mission the new ASN Commission held its first meeting. This was one of the first steps in the implementation of the new Transparency and Nuclear Safety (TSN) 2006 Act. The IRRS Review Team recommends the full implementation as soon as practicable of the requirements and powers given to ASN by the new TSN 2006 Act and 2006 Waste Act through elaboration of the necessary Decrees and Orders, and the implementation of the new enforcement powers.

ASN should continue to develop and sustain the technical expertise to ensure that the products and services provided by IRSN are technically adequate (the 'intelligent customer' capability).

The IRRS Review Team believes that consideration of the following items should be given high priority either because they were identified in several areas of review or because the experts considered that they will contribute significantly to the enhancement of the overall performance of the regulatory system:

- Formalization of existing and established procedures, approaches and guides and preparation of such in some areas (e.g. enforcement, radiation protection), and further development and implementation of a management system consistent with IAEA safety standards;
- Continued upgrading of post-accident planning;
- The ready availability of and access to occupational radiation exposure results by monitored individuals, employers and ASN;
- A human resources strategy, in particular in maintaining the regulatory competence levels of ASN in light of the current wider French policy of staff rotation;
- Feedback of operating experience into regulatory programmes;
- Time frame for onsite implementation; and
- Harmonization of waste management regulations.

The IRRS Review Team findings are summarized in Appendix VI.

There was a strong consensus among the IRRS Review Team that France and IAEA Member States have been improving the regulation of nuclear and radiation safety worldwide through IAEA regulatory review missions. This first IRRS full scope mission will give considerable impetus to the start of a series of missions that will enhance nuclear and radiation safety by improving regulatory organizations and practices.

I. INTRODUCTION

At the request of the French Government Authorities, an IAEA team of twenty four experts consisting of experts from sixteen Member States among them two observers, and six staff members from the IAEA and an IAEA administrative assistant visited the Autorité De Sûreté Nucléaire (ASN) in November 2006 to conduct a full scope Integrated Regulatory Review Service (IRRS). In May 2006 a preparatory mission had been carried out at ASN headquarters, Paris, to discuss the objective and purpose of the review as well as its scope in connection with all aspects of the new French regulatory authority.

The purpose of the mission was to conduct a review of the entire French regulatory framework and the regulatory activities in all regulated facilities and practices, to review the effectiveness of ASN and to exchange information and experience in the regulation of the areas considered by IRRS. The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; emergency preparedness; radioactive waste management; the management system; transport (as a follow-up to an IAEA Transport Safety Appraisal Service – TranSAS); and public information and communication.

In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of nuclear, radiation, radioactive waste and transport safety. Regulatory technical and policy issues were identified after reviewing a broad spectrum of information including insights resulting from the conclusions of the Nuclear Safety Convention review meetings, international conferences and forums and previous IAEA safety review services.

The mission was conducted from 6 - 17 November 2006. Before the mission, ASN made available a collection of advance reference material for the team to review. This material consisted of a large number of legal, regulatory and internal documents, in particular the report on self-assessment including the IAEA questionnaire. During the mission the team performed a systematic review of all topics using the report on self-assessment, the advance reference material, interviews with ASN staff and direct observation of their working practices during inspections carried out by ASN.

IRRS activities took place mainly at the ASN headquarters, Bourgoin, and its offices at Fontenay-aux-Roses, ASN DSNR Paris, Ile de France., ASN DSNR Nantes, Pays de Loire, ASN DSNR Dijon, Bourgogne, ASN DSNR Chalons-en-Champagne, Champagne-Ardennes, ASN DSNR Caen, Basse-Normandie and ASN DSNR Lyon, Rhone-Alpes. Site visits for facilities, activities and practices took place in several areas; visits were made to nuclear power plants, research reactors, fuel cycle facilities, medical activities and practices, industrial sources and waste disposal facilities (see Appendix III).

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct a full-scope IRRS mission to review the French legal and governmental infrastructure for nuclear, radiation, radioactive waste and transport safety and the effectiveness of the French regulatory body (ASN) and to exchange information and experience among ASN and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The key objectives of this mission were to enhance nuclear and radiation safety by:

- ✓ Providing the host country (regulatory body and governmental authorities) with a review of their nuclear and radiation safety regulatory technical and policy issues;
- ✓ Providing the host country with an objective evaluation of their nuclear and radiation safety regulatory practices with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting sharing of experience and exchange of lessons learnt;
- ✓ Providing key staff in the host country with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing the host country with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review;
- ✓ Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field; and
- ✓ Providing the host country through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards.

The scope requested by France for this IRRS mission was:

- Safety of fuel cycle facilities (enrichment by diffusion, fuel fabrication, reprocessing);
- Safety of nuclear power plants (PWR);
- Safety of research reactors and research laboratories;
- Radiation protection in industrial practices and research;
- Safety in the transport of radioactive material (follow-up TranSAS mission);
- Occupational radiation protection;
- Radiation protection in medical practices (diagnostic radiology, interventional use of X-rays, nuclear medicine and radiotherapy);
- Control of public exposures;
- Workplace exposure to natural sources of radiation;
- Radioactive waste management;
- Decommissioning of nuclear facilities;
- Remediation of contaminated sites;
- Environmental radiological protection ;
- Emergency preparedness;
- Safety of nuclear pressurized equipment; and
- Communication and public information

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the mission was carried out by the IRRS IAEA Coordinator Gustavo Caruso, NSNI/ IAEA, and by the IRRS Deputy Coordinator Khammar Mrabit, NSRW/IAEA. It is important to mention that, for the first time, both the IRRS Team Leader, Mr. Len Creswell, and the IRRS Deputy Team Leader, Mr. Andrew McEwan, belong to IAEA Member States rather than being IAEA staff. In accordance with the request from ASN, and taking into account the scope as indicated above, it was agreed that the IAEA review team would be comprised of 15 external experts and 2 observers from 16 Member States (see Appendix I). The working areas and the ASN counterparts were distributed according to Appendix V).

During the preparatory period all documents of the advance reference material (ARM) were sent electronically by ASN to the IAEA and distributed to the experts. All details and organizational aspects were defined with the nominated ASN Counterparts – Liaison Officer Mr. Philippe Bordarier and Deputy Liaison Officer Jean-René Jubin.

A significant amount of work was carried out by the reviewers and by the IAEA staff before the review in order to prepare the initial impressions about the ARM, to review the answers to the questionnaire sent to ASN, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary to review during the mission.

An entrance team meeting was conducted on 5 November in the ASN headquarters by the IRRS Team Leader, the IRRS IAEA Coordinator and the IRRS Deputy Coordinator to discuss the specifics of the mission, to clarify the basis for the review, background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. The reviewers also reported their first impression on the advance reference material.

B) REFERENCES FOR THE REVIEW

The main reference documents provided by ASN for the review mission are indicated in Appendix VII. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VIII.

C) CONDUCT OF THE REVIEW

During the mission, a systematic review was conducted for all the review areas with the objective of providing ASN with recommendations and suggestions as well as of identifying good practices. The review was conducted through meetings, interviews and discussions with ASN personnel, visits to relevant organizations, assessment of the ARM, and direct observations regarding the national practices and activities, particularly in the context of inspections.

The team performed its activities based on the Mission Programme given in Appendix II.

The entrance meeting was held on Monday 6 November with the participation of ASN senior management. Opening remarks were made by Mr. Andre-Claude Lacoste, recently appointed Chairman of ASN, and Mr. Aybars Gürpinar, Acting Director, Division of Nuclear Installation Safety, Department of Nuclear Safety and Security, IAEA. Mr. Michel Bourguignon, ASN Deputy Director General (recently appointed as ASN Commissioner), Mr Jean-Luc Lachaume, ASN Deputy Director General and Mr. Alain Schmitt, ASN Deputy Director General also participated in the entrance meeting.

The exit meeting was held on Friday 17 November with the ASN authorities, Mr. Andre-Claude Lacoste, ASN Chairman, and the recently nominated ASN Commissioners, Mr. Bourguignon, Mr. Sanson, Mr. Barthelemy and Ms. Combes-Comets, Department Heads, Division Heads, Section

Heads, technical staff and support staff. The main conclusions were presented by the IRRS Team Leader, and closing remarks were made by Mr. Tomihiro Taniguchi, IAEA Deputy Director General, Department of Nuclear Safety and Security. The draft technical notes were handed over to ASN at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1. GENERAL

Legislative and statutory framework

GS-R-1 § 2.2 (1)

In France the legislative and statutory framework established to regulate the safety of facilities and activities has been developed over several decades, and like many other states has its origins in the early nuclear power programme developed by Government agencies, departments, commissions and ministries. The nuclear regulatory authority in France was created in 1973 as a department of the Ministry of Industry and then in 1991 became the DSIN, a Division of the Ministry of Industry; since that time the responsibilities of the Ministry of the Environment increased, and the DSIN answered jointly to both Ministries.

In 2002 a new Decree created the Directorate General for Nuclear Safety and Radiation Protection (DGSNR) answering to both the Ministries of Industry and the Environment and with responsibilities for both nuclear and radiation safety. The new 2006 TSN Act creates ASN as an independent administrative authority, as part of the French State, and answering to Parliament – as required by the French Constitution. The new ASN Commission met for the first time on Monday 13 November 2006, and can now demonstrate effective independence from organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. The new ASN Commission now has the opportunity to fully implement the requirements and the powers given to it by the new TSN 2006 Act through elaboration of the necessary decrees and orders to fully clarify and enhance its independent status, and has put into place new enforcement powers. The legislative framework is described in more detail in following paragraphs.

Law No. 61-842 of 2 August 1961 on Atmospheric Protection and Malodour Control (lastly amended by Ordinance No. 2000-916 of 19 September 2000), and Decree No. 63-1228 of 11 December 1963 and Decree 95-54 of 4 May 1995 related to Basic Nuclear Installations (BNIs), introduced provisions for controls on emissions from power reactors and related facilities and requirements governing the establishment and authorization of BNIs. Controls on nuclear facilities were further defined in the Order of 10 August 1984 concerning Quality of Design, Construction and Operation of Basic Nuclear Installations, and the Order of 31 December 1999 setting out general technical rules to prevent and limit pollution and external risks resulting from the operation of major nuclear installations. A new law Act No. 2006-686 of 13 June 2006 (TSN 2006 Act) on transparency and safety in the nuclear field has been introduced. This gives a better legislative base for nuclear safety, clarifies and enhances the independent status of the Nuclear Safety Authority (ASN), and provides it with new enforcement powers.

Legislation relating specifically to radiation safety has been the responsibility of ASN only relatively recently from 2002. Ordinance No. 2001-270 of 28 March 2001 is concerned with the implementation of EU directives in the field of protection against ionizing radiation (and is now codified in Chapter III of Title III of Book III of the Public Health Code, Legislative part, L-1331-1 to 20). Decree No. 2002-460 of 4 April 2002 relates to public protection against ionizing radiation (and is now codified in the regulatory part of the Public Health Code, which contains in Articles R-1333-1 to 93 regulations made under L-1331-1 to 20). Decree No. 2003-296 of 31 March 2003 relates to the radiation protection of workers. (This Decree has amended the Labour Code to introduce a new section 8). Decree 2002-255 of 22 February 2002 amending decree 93-1272 of 1 December 1993 and creating the Directorate General for Nuclear Safety and Radiation Protection (DGSNR) gave this directorate responsibility - under the authority of the Ministers for Health, the Environment and Industry - for defining and implementing nuclear safety and radiation protection

policy. The TSN 2006 Act (in Art.3 1(b)) also confers responsibility for implementation of the Health Code radiation protection provisions on ASN.

The legislative part of the Health Code sets out principles of radiation protection, requirements for notification of overexposures, notification and authorization of radiation sources, emergency planning, exposure monitoring, and initial and continuing theoretical and practical training on the protection of persons exposed for medical purposes for professional persons performing radiodiagnostic, radiotherapeutic or nuclear medicine procedures for the purposes of diagnosis, treatment or biomedical research, and other provisions.

The French Health Product Safety Agency (AFSSAPS) is a state institution under the authority of the Minister for Health. It takes part in implementing laws and regulations concerning all activities affecting health products intended for use by man, as well as cosmetic products, and in particular drugs, biomaterials and medical devices, in-vitro diagnostic medical devices, including those using ionizing radiation. With regard to health products that generate radiation, the AFSSAPS issues radiation protection authorizations for distribution of radio-pharmaceuticals and registers notifications of new medical devices emitting ionizing radiation (radioactive sources and electrical equipment generating X-rays). It is also responsible for organizing the supervision of medical devices and, in particular, issues certification for the organizations in charge of this supervision and defines the standard compliance requirements for quality controls of each equipment category.

The Labour Code in Article L231-7-1 sets out provisions relating to the **protection of workers** against the risks of exposure to ionizing radiation. These are defined in compliance with the general principles of radiation protection of persons laid down in article L. 1333-1 of the Public Health Code. Regulations made under Article L231-7-1 are given in Article R231-73 to 113 of the Labour Code. These provisions provide general health prevention rules addressed in art. L. 230-1 and seq. of the Labour Code.

Regulations on **radiological emergencies** were introduced in Decree No. 2003-295 of 31 March 2003 and Decree No. 2005-1179 of 13 September 2005, and included in the regulatory part of the Public Health Code. An Inter-ministerial Directive was issued on 7 April 2005 on the Action of the Public Authorities in the Event of an Emergency.

Radioactive waste management in France became subject to specific legislative controls through Law No. 91-1381 of 30 December 1991 on research on radioactive waste management (now codified in articles L542-1 to L542-14 of the Environment Code). Decree No. 92-1311 of 17 December 1992 implemented Article 6 of Law No. 91-1381. Decree No. 92-1391 of 30 December 1992 (lastly amended by Decree No. 2005-384 of 25 April 2005) created the Agence nationale pour la gestion des déchets radioactifs (National Agency for Radioactive Waste Management, ANDRA). Decree No. 93-940 of 16 July 1993 further implemented Law No. 91-1381 of 30 December 1991 on research on radioactive waste management and on introducing requirements for the establishment and operation of an underground laboratory (lastly amended by Decree No. 2003-1264 of 23 December 2003). An Act "National Policy for the Management of Radioactive Materials and Wastes" was introduced on 15 June 2006.

The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes defines (i) the national policy for the management of radioactive materials and wastes, (ii) the organization and funding of the management of radioactive materials and wastes, and (iii) provides for controls and sanctions. Article 2 stipulates: *"radioactive materials and wastes of whatever nature... are managed sustainably with due regard to the protection of personal health, safety, and the environment. To avert or limit the burden that will be borne by future generations, research is undertaken and the necessary means for the definitive securing of radioactive waste are implemented. Producers of spent fuels and radioactive wastes are responsible for these substances without prejudice to the responsibility their holders have as nuclear activity operators"*. The Act

defines a research programme, with target dates for disposal of wastes that are not acceptable in the existing repositories. It legalizes the principle and the objectives of the national plan for the management of radioactive materials and wastes. It also sets requirements with regard to the funds necessary for dismantling and long-term management of waste.

Establishment of an effectively independent regulatory body

GS-R-1 § 2.2 (2)

Decree 2002-255 of 22 February 2002 amended Decree 93-1272 of 1 December 1993 and created DGSNR, giving it responsibility for regulating the safety of BNIs, radioactive material transport and radiation protection. Occupational exposure control is governed by the Labour Code (administered under the Minister of Labour) and protection of the public by the Public Health Code (Minister of Health). The ASN has responsibility to exercise the controls under this Code. At present there is not a clear separation between the Labour Ministry and ASN inspections, but work is proceeding on clarification of functions. For example, ASN is currently discussing with the Labour Ministery to plan joint inspections. In NPPs the DGNSR has an exclusive control and inspection role (TSN 2006 Act, Article 57).

The DGSNR was established under the supervision of the Ministers for the Environment and Industry with regard to the safety of BNIs and radioactive material transportation, and of the Minister for Health with regard to radiation protection (other than for workers).

This multiple supervision, provided for independence of the DGSNR from the Directorate General for Energy and Raw Materials, which has responsibility for nuclear energy development and reports exclusively to the Minister for Industry. In cases of discrepancy between the supervisory ministers, the Prime Minister's services convened a meeting with the supervisory ministers and the DGSNR to make the final governmental decision.

The DGSNR coordinated and supervised the activities of the Nuclear Safety and Radiation Protection Divisions (DSNR) of the Regional Directorates for Industry, Research and the Environment (DRIRE), and also relies on the Regional and Departmental Health and Social Action Directorates (DRASS and DDASS) for supervision of radiation protection related to the control of radon exposures and of radiological quality of drinking water, in accordance with the provisions of article 2-V of Decree 2002-255 of 22 February 2002. The DGSNR together with the decentralized departments for which it organizes and supervises activities in its area of competence, is referred to as the "Nuclear Safety Authority" (Autorité de sûreté nucléaire, ASN).

The Head of the DGSNR was appointed by the President on the recommendation of the Prime Minister and Ministers responsible for Industry, the Environment and Health. His appointment had no time limit although it could be revoked at any time.

The responsibilities and subsequent powers which Decree No. 2002-255 granted to the DGSNR allowed it to carry out its functions with large degree of autonomy from the supervisory Ministers. Also, the Director General was delegated some signatory authority by the supervisory Ministers.

The new TSN 2006 Act created a Commission of ASN as an independent administrative authority, not answering to Ministers of Government, but part of the French State answering to Parliament. It therefore no longer reports to the Ministers of Industry and the Environment. The ASN, under this Law, has authority to develop regulations although some of them must still be approved by the competent ministers for nuclear safety and radiation protection as required by the French constitution.

Decrees are required for the establishment of NPPs. These are signed by the Minister of Industry as a legal regulatory instrument, and are for the purpose of the creation of the installation. The authorizations for operation and discharge limits are issued by ASN.

The ASN budget is prepared by ASN, submitted to the Government and approved by the Parliament. Under the TSN 2006 Act the Chairman of the Commission is appointed by the President and holds office for a fixed term (TSN 2006 Act, Art. 10).

Regulatory body - assigned responsibilities, authority, and resources

GS-R-1 § 2.2 (3), (4) & (5)

The legislation assigns responsibility to ASN for:

- authorization;
- regulatory review and assessment;
- inspection and enforcement;
- establishing safety principles, criteria, regulations and guides; and
- communication and public information

The legislation consists of Ch.3 of TSN 2006 in regard to the inspection and enforcement for NPPs.

The Team was informed that the ASN budget provides adequate staffing and financial resources for ASN to discharge its duties, including expansion to cover responsibilities for the new ASN activities in radiation protection. Since gaining these additional responsibilities, the ASN has been recruiting at a rate of about 20 new staff positions per year, and this is to continue for several more years.

Adequate legal and governmental mechanisms are in place to ensure that no other responsibilities are assigned to the Regulatory Body which might jeopardize or conflict with its responsibility for regulating safety (through the TSN 2006 Act).

An area that could benefit from clarification is the respective roles and responsibilities of ASN and the Ministry of Labour with respect to occupational exposure and radiation protection of workers, noting that this is currently being addressed (see above).

GS-R-1 § 2.2 (6), (7)

Adequate legal and governmental mechanisms are in place to ensure adequate infrastructural arrangements for decommissioning, for close out or closure, site rehabilitation, and safe management of radioactive waste (through Decree 63-1228, Law 2003-699 30/07/03 and the Order of 31 December 1999), and for the safe transport of radioactive material.

GS-R-1 § 2.2 (8)

ASN is fully involved in the system of governmental emergency response and intervention capability to assure effective emergency preparedness in France. ASN organizes emergency exercises several times a year. A review was carried out last year of the inter-ministerial orders relating to emergency response.

ASN is the competent authority for international conventions relating to emergencies.

GS-R-1 § 2.2 (9)

ASN does not have responsibility for security of materials.

However a memorandum of understanding has been established with the body responsible for security.

GS-R-1 § 2.2 (10)

France is a signatory to the Paris and Brussels Conventions on Third Party Indemnity in the event of an accident from a nuclear installation. For non-nuclear facilities compensation is available through the Civil Code.

Operator responsibility

GS-R-1 § 2.3

The prime responsibility for nuclear and radiation safety is clearly assigned to the operator through Article 4 of the 10/08/1984 Order and the new TSN 2006 Act.

Legislative requirements

GS-R-1 § 2.4

Legislation has been promulgated in France that provides for effective control of nuclear, radiation radioactive waste and transport safety.

GS-R-1 § 2.4 (1)

The legislation sets out effective objectives for protecting individuals, society and the environment from radiation hazards in the Public Health Code (Article L.1333-1 of which defines the 3 principles of radiation protection: justification, optimization and limitation of doses), and the Environment Code.

GS-R-1 § 2.4 (2)

The legislation specifies facilities, activities and materials that are included in its scope, and provides for some exemptions. See Article R1333-27 of the Public Health Code.

GS-R-1 § 2.4 (3)

The legislation establishes authorization and other processes (such as notification), which take account of the potential magnitude and nature of the hazard associated with the facility or activity, and specifies the steps of the processes. For BNIs Decree n°63-1228 on December 11, 1963, modified, defines the authorization process and takes into account the potential magnitude and nature of the associated hazards. Its article 2 defines the facilities that are included. Article 3 prescribes the procedure. For other practices notification or authorization is required.

GS-R-1 § 2.4 (6)

Legislation specifies the process for removal of BNIs from regulatory control, but treats clearance aspects on a case by case basis.

GS-R-1 § 2.4 (7)

Appeals against regulatory decisions follow the rules applying for challenging any administrative decisions: the plaintiff must present a request before the authority which made the decision or its supervisory authority and if the request is rejected, the plaintiff may appeal against this latter decision before administrative courts. In the case that it is an authorization granted by Decree which is challenged, the procedure will be before the Council of State, i.e. the highest administrative court in France (Article R311-1 of the Code of Administrative Justice). Art. 45 of the TSN 2006 Act refers to Code of Administrative Justice actions.

For NPP operators there is no appeal against ASN technical decisions. However, there are multiple exchanges of information prior to a decision being made.

GS-R-1 § 2.4 (8)

Legal requirements governing continuity of responsibility when activities are carried out by several successive operators are defined in Article 6 of Decree n°63-1228, which requires a new authorization for the facility.

GS-R-1 § 2.4 (9)

The Decision of 27 March 1973, amended by the Decision of 1st December 1998, sets up standing advisory committees (Groupes permanentes) reporting to the DGSNR, with responsibility for examining the technical problems arising in the nuclear safety area. The composition of these committees ensures their independence. See also Section 3.3 for further detail. Advisory committees to the ASN exist for reactors, transport, pressure vessels, other installations and waste. A further committee is proposed to advise on radiation protection issues, which were previously covered by the Office for Protection against Ionising Radiation (OPRI), the Commission for artificial radionuclides (CIREA) and the General Directorate for Health (Health Minsister).

Additionally advice from the Inter-ministerial Commission for Basic Nuclear Installations (CIINB), an inter-ministerial advisory committee formed by the Decree n° 63-1228 of 11/12/1963, is required to create or modify any basic nuclear installation.

Further, the Decree n° 02-254 sets up the Institut de radioprotection et de sûreté nucléaire (IRSN) which provides technical support for the DGSNR. The independence of IRSN is provided for by having its senior management board report to a number of different Ministers, as prescribed in this Decree. IRSN is Government-funded. The relationship between ASN and IRSN is set out in a charter. See also section 3.3 for further detail.

GS-R-1 § 2.4 (10)

The legislation does not clearly establish a means whereby research and development work is undertaken in safety areas. Article 8 of the TSN 2006 Act indicates ASN is to carry out technical investigations on request of Government, Ministers, or the Parliamentary Office for Science and Technology Assessment. Such studies would generally be conducted in-house although could be undertaken by IRSN as a provider of technical support for ASN.

GS-R-1 § 2.4 (12), (13)

In the TSN 2006 Act there is a requirement on operators for provision of financial security in respect of any liabilities (Article 29, 1st paragraph). The funds must exist within the organization.

In the 2006 Sustainable Management of Radioactive Materials and Wastes Act there are requirements in Article 20 II on BNI operators to establish reserves for decommissioning, waste disposal and closure. In particular the Act:

- defines the obligations of operators (such as prudent cost estimation, and separate funding and accounting for closure and waste management)
- establishes the principle of protection of the funds against creditors
- establishes a control agency (a national financial evaluation Commission) and stipulates measures to assure the financial situation of the operator, if necessary
- requires the Commission of ASN to report to Parliament and to the High Committee for Transparency and Information on Nuclear Safety (created by the TSN 2006 Act) every three years presenting its assessment of the adequacy of the reserves and the management of the funds.

GS-R-1 § 2.4 (14)

Chapter IV of the TSN 2006 Act defines what is an offence and the corresponding penalties.

GS-R-1 § 2.4 (15)

France implements IMDG, ICAO, ADR, RID, ADNR requirements through Ministerial Orders.

It is a signatory to the:

- Paris and Brussels Conventions: Law No. 68-943 of 30 October 1968;
- CPPNM (published by Decree No. 92-110 of 3 February 1992): Law No. 80-572 of 25 July 1980 on Control and Protection of Nuclear Materials, as amended (now codified in Articles L.1333-1 to L.1333-14 of the Code of Defence; decree No. 81-512 of 12 May 1981 related to the Control and Protection of Nuclear Materials;
- Notification and Assistance Conventions (published by Decrees No. 89-360 and 89-361 of 2 June 1989): Decree No. 2003-295 of 31 March 2003 and Decree No. 2005-1179 of 13 September 2005 on radiological emergencies (introduced into the regulatory part of the Public Health Code);
- Nuclear Safety Convention: Decree No. 63-1228 of 11 December 1963; 2006 TSN Act; and
- Joint Convention (published by Decree No. 2001-1053): Decree No. 63-1228 of 11 December 1963; Law No. 91-1381 of 30 December 1991 (now codified in Articles L542-1 ff of the Code of the Environment).

In addition an Inter-ministerial Directive of 7 April 2005 relates to the Action of the Public Authorities in the Event of an Emergency; and Inter-ministerial Directive of 30 May 2005 to the Implementation of the International Convention on Early Notification of a Nuclear Accident. There is an Inter-ministerial Directive on the Implementation of the Assistance Convention.

Directive 96/29/Euratom is implemented in Articles L. 1333-1 ff and R. 1333-1 ff of the Public Health Code.

GS-R-1 § 2.4 (16)

Scope for public debate on establishment of major facilities is provided for in general environment law. For BNIs a public enquiry is mandatory. The TSN 2006 Act requires that all documents of the operator be made available to the public (subject to security and confidentiality considerations), and that the ASN must consult the Local Information Committee on siting and other matters (Art. 22 V).

A public debate has taken place regarding the first EPR installation. Steps in this included:

- Inter-ministerial consultations relating to the licensing process pursuant to Decree No. 63-1228 and Decree No. 95-540
- Consultations with local authorities, including the Prefect and local councils relating to authorization procedures, the local water commission, the Health Departmental Council and the “mission déléguée de bassin” in the discharge authorization procedure, pursuant to Decree 63-1228 and Decree 95-540
- Public hearings pursuant to Decree 63-1228 and Decree 95-540 (for most of the authorization procedures).

GS-R-1 § 2.4 (17)

Mechanisms exist for newly established legal requirements to be made applicable to existing facilities and current activities. Newly established requirements can be of two types:

- legally binding documents (Ministerial Orders): in this case, the Order defines the way the regulation is applicable to already existing plants, and can fix time limits to achieve compliance ;

- general recommendations, such as "basic safety rules", which are not mandatory. In this case, their implementation for BNIs is generally examined in the frame of the periodic safety review, and they are made applicable to the existing installations on a case by case basis.

A Decree implementing the TSN 2006 Act is expected in early 2007 and will contain transitional provisions. Retroactive action depends on the significance of any changes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** (1) GS-R-1 Section 2.2(2) states *"A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgments can be made, and enforcement actions taken, without pressure from interests that may conflict with safety"* (2) GS-R-1 Section 2.4(14) states the legislation *"shall define what is an offence and the corresponding penalties;"* (3) GS-R-1 Section 2.6(8) states *"The regulatory body shall have the authority to enforce regulatory requirements;"*

R1 **Recommendation**: In order to fully clarify and enhance its independent status, and put into place the new enforcement powers, ASN should as soon as practicable fully implement the requirements and the powers given to it by the new TSN 2006 Act through elaboration and implementation of the necessary Decrees and Orders.

(1) **BASIS:** GS-R-1 Section 2.2(11) states *"The technological infrastructure necessary for ensuring the safety of facilities and activities shall be provided, where this is not provided by other organizations".*

R2 **Recommendation:** Although ANDRA has some responsibility in this area, ASN should continue its work to clarify and formalize the arrangements to ensure safety e.g. for "orphan" sources.

(1) **BASIS:** GS-R-1 Section 2.4(9) states the legislation *"shall allow for the creation of independent advisory bodies to provide expert opinion to, and for consultation by, the government and regulatory body;"*

G1 **Good Practice:** ASN makes extensive use of independent expert advisory committees on a variety of topics and themes in many areas. These advisory committees include experts from other countries.

(1) **BASIS** GS-R-1 Section 2.4(10) states the legislation *"shall set up a means whereby research and development work is undertaken in important areas of safety;"*

R3 **Recommendation**: ASN should consider development of its input into and formal monitoring of research and development in nuclear and radiation safety.

(1) **BASIS** GS-R-1 Section 2.4(16) states the legislation *"shall define how the public and other bodies are involved in the regulatory process;"*

G2 **Good Practice:** The environment law provides for Public Debate and Public inquiries on the establishment of major facilities. ASN provides full information e.g. to Local Information Committees as part of this process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** (1) GS-R-1 section 2.2(6) states *"There are certain prerequisites for the safety of facilities and activities. These give rise to the following requirements for the legislative and governmental mechanisms of States: …. (6) Adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste."* (2) GS-R-1 section 2.4(13) states "*Legislation shall be promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transport safety. This legislation: … (13) shall set out the responsibilities and obligations in respect of financial provision for radioactive waste management and decommissioning"*

S1 **Suggestion:** The ASN should interact with the administrative authority which controls the funds for radioactive waste management and decommissioning to make technical competence available and to provide assessments of feasibility and other aspects of plans that can underpin decisions on financing made by the administrative authority.

(1) **BASIS:** (1) GS-R-1 Section 2.2(3) states "*Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides."*

(2) GS-R-1 Section 2.2(4) states "*The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities."*

R4 **Recommendation:** The clarification of interaction between the Ministry of Labour and ASN concerning the radiation protection of workers should be carried out.

1.2 AUTHORITY OF THE REGULATORY BODY

GS-R-1 § 2.6 (1)-(14)

ASN has the authority to develop safety principles and criteria, and to develop regulations and issue guidance.

For BNIs the legislation (through Article 5 Decree 63-1228, and the TSN 2006 Act Article 29) ensures that the Regulatory Body has the authority to require an operator to conduct a safety assessment at any time.

The legislation gives the ASN the authority:

- to require an operator to provide any necessary information, including information from its suppliers, even if this information is proprietary. (The TSN 2006 Act Article 40 III allows nuclear safety inspectors to request any information, and the regulations detail requirements for providing information in applying for authorizations).
- to issue, amend, suspend or revoke authorizations and to set conditions (In Article 12, 13 of Decree 63-1228 for BNIs. The TSN 2006 Act extends powers to all facilities (Article 3 6 (g).)
- to require a BNI operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities; (In Article 5 of Decree 63-1228).
- to enter a site or facility at any time to carry out an inspection. (The French legislation (1976 Environment Code) relating generally to industry inspections gives the right to an inspector to enter a site or a facility at any time to carry out an inspection. The Decree of 2004 amending the Public Health Code specifically includes non-nuclear sites).
- to enforce regulatory requirements. (ASN can use different legal tools to enforce regulatory requirements including authorization revocation. The ASN power in this area is reinforced with the TSN 2006 Act.)
- to communicate directly with governmental authorities at higher levels when it is considered necessary for exercising effectively the functions of the Regulatory Body. (The TSN 2006 Act creating the ASN as an independent authority confers freedom to communicate at will. This includes communicating independently its regulatory requirements, decisions and opinions and their basis to the public. The ASN provides information dealing with several topics, including incidents. A lot of information is available on its website. For non-urgent topics, information is given to national and international organizations on a case by case basis. In the framework of emergency preparedness, protocols are signed (or are still being drafted) with multinational or foreign organizations, such as counterparts of neighbouring foreign countries.)
- to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods. While no specific legislative provision exists liaison occurs widely in practice. Formalized arrangements are being pursued.

The requirements of GS-R-1, para. 2.6 appear to be met, and hence the team has no specific recommendations or suggestions with respect to the authority of ASN.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Regulatory body - fulfilling statutory obligations

GS-R-1 § 3.1

The ASN as the Regulatory Body has defined policies, safety principles and associated criteria as a basis for its regulatory actions set out in regulations and guides. IAEA standards are incorporated into these. A review is being carried out against the Western European Nuclear Regulators Association (WENRA) reference levels.

GS-R-1 § 3.2 (1)

There are basically two types of general regulations and guidance (by general is meant applicable to several practices or facilities, and not regulations that are issued just for one facility, such as an authorization decree for a BNI).

- Legally binding regulations: these are Decrees and Ministerial Orders relating to BNIs and other practices. They are drafted by ASN, and then sent for comments to the licensees, manufacturers, professional societies and IRSN, as appropriate. In the case of BNIs, before formal approval, they are submitted to a Commission (CIINB) in which the stakeholders are mainly licensees and representatives of the administration.
- General recommendations, mostly "basic safety rules", but also guides and DGSNR notes. They are drafted either by ASN, or by a working group composed of ASN, IRSN, licensees and professional societies. If their technical nature justifies it, they are presented to the committees advising ASN. Comments from stakeholders are also sought.

In the past, the need for new regulations was identified on the basis of feedback from operating and regulatory experience. Now, the main driving force is European harmonization.

Guidance and codes are under development for medical practices. Information related to code development is placed on the website. Code development proceeds on the basis of consultation with user groups and professional or sector groups and associations.

GS-R-1 § 3.2 (2)

ASN reviews and assesses submissions on safety of BNIs prior to authorization (Decree 63-1228). For other types of practice, review of safety occurs on renewal of authorization, but otherwise there is no requirement.

Applications for authorizations and declarations to use medical devices emitting radiation, including X-ray equipment, must include safety reports on the equipment and facilities as required by APSSAPS.

GS-R-1 § 3.2 (3) (i)-(x)

When issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, ASN specifies:

- The requirements for notifying ASN of any modifications to safety related aspects.
- The obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel.
- Limits on operation and use, (such as, for BNIs, dose or discharge limits, action levels or limits on the duration of the authorization).
- Conditioning criteria for radioactive waste processing for existing or foreseen waste facilities. (For example in the Order of 31 December 1999 relating to releases from BNIs).

- Any additional separate authorizations that the operator is required to obtain from the ASN as necessary.
- The requirements for incident reporting. The Public Health Code requires reporting of any incident to authorities (Prefect, ASN, etc.). For BNIs this requirement is in Decree 63-1228 and the Order of 10 August 1984.
- The reports that the operator is required to make to ASN for BNIs. Incident reporting guidance is under development for non-nuclear facilities.
- For BNIs, the records that the operator is required to retain and for how long (in the quality Order (10 August 1984)).
- The emergency preparedness arrangements. To obtain a BNI licence, a company has to provide ASN with an on-site emergency plan. These arrangements are reviewed by ASN.

GS-R-1 § 3.2 (4)-(6)
The ASN carries out regulatory inspections, ensures that corrective actions are taken if unsafe or potentially unsafe conditions are detected, and for BNIs can take the necessary enforcement action in the event of violations of safety requirements.

Regulatory body – discharging its main responsibilities

GS-R-1 § 3.3 (1)-(5)
The ASN

- has established a process for dealing with applications, such as applications for the issuing of an authorization, accepting a notification, or for the removal from regulatory control. The processes are established by regulations and apply also to changing conditions. In addition, internal guidance is used by ASN. Some of the processes include consultation with public and administrative departments and operators. Advice from advisory committees is also taken into account.
- provides guidance to operators on developing and presenting safety assessments and other required safety related information in "Guide de l'ASN" which gives an outline of the information to be provided. In medical and other non-nuclear areas guides are being developed in consultation with professional bodies.
- ensures that sensitive information such as proprietary information is protected. The protection of sensitive information is covered by 78-753 Act of 17/7/1978 modified by the 2005-1319 Act. The arrangements have been incorporated in the Environment Code (chapter IV)
- provides an explanation of the reasons for the rejection of a submission through ASN decision letters. These letters are published on the ASN website.

GS-R-1 § 3.3 (6)
ASN communicates with, and provides information to other competent governmental bodies, international organizations, and the public. It provides extensive information on its criteria and decisions on its website.

GS-R-1 § 3.3 (7)
Regulations require notification and assessment of events (relating to safety, radiation protection and the environment). Criteria are set for classification of event severity. Approximately 600 events are notified for NPPs every year. Analysis reports are reviewed, and assessed if needed by IRSN. Further analysis or corrective action can be required from the licensee. Implementation of corrective actions is checked during inspection, as well as the effectiveness of the detection, analysis and feedback process throughout the licensee's organization. A similar procedure is followed for other practices.

The personal dosimetry service operated by IRSN has some technical problems resulting in irregular reporting. This service is provided on behalf of the Minister of Labour, who is viewed as the client for the service, and prompt reporting to ASN has not, to date, occurred.

GS-R-1 § 3.3 (8)
There are legal requirements for records relating to the safety of facilities and activities to be retained and retrievable. ASN carries out regulatory inspections of records.

GS-R-1 § 3.3 (9)
Prior to the issue of new regulations, ASN consults widely, including with licensees, and also requests advice from IRSN and, as necessary from advisory committees, to ensure the validity and adequacy of regulatory principles and criteria. ASN takes into consideration internationally endorsed standards and recommendations. The radiation protection regulations are based on the Euratom Directive 96/29, which includes international standards and recommendations, in particular those of IAEA and the ICRP. For example, the general principles of radiation protection (justification, optimization, limitation), defined internationally (ICRP) and included in directive 96/29 are enshrined in the Public Health Code (Article L.1333-1) and guide the regulatory action for which ASN is responsible. ASN is also incorporating WENRA reference levels in its regulations.

GS-R-1 § 3.3 (10)
ASN establishes and informs the operator of NPPs of any requirements for systematic safety reassessment or periodic review. Letters are sent to licensees to detail what will be the scope of each periodic safety review (PSR), including items to be analysed regarding the changes to regulations or guides, operating experience feedback and management of ageing.

GS-R-1 § 3.3 (11):
ASN advises the Government on matters relating to the safety of facilities and activities as required by Decree 2002-255 and the TSN 2006 Act.

GS-R-1 § 3.3 (12)-(13):
The ASN does not directly confirm the competence of personnel responsible for the safe operation of a facility or activity. The competence of staff of BNIs is a licensee responsibility through a requirement of the Order of 10/08/1984 relating to quality. However, ASN assesses operator procedures, and also safety management, through inspections, incident management and the authorization process. Provisions about qualifications are addressed in Art. R. 1333-29 of the Health Code.

In medical practices the regulatory requirements for qualified persons, including approved organizations, are checked through inspections and the authorization or declaration processes.

Regulatory body – cooperation with other relevant authorities

GS-R-1 § 3.4
The ASN cooperates with other relevant national authorities, advises them and provides information in all the above areas, as necessary, with the exception of physical protection and safeguards.

The ASN also interacts with other national agencies, such as AFSSAPS, which operates under the authority of the Ministry of Health.

Regulatory body – additional functions

GS-R-1 § 3.5
ASN does not have additional functions such as independent radiological monitoring in and around nuclear facilities, providing personnel monitoring services, conducting medical

examinations, independent testing or quality control measurements, and therefore does not have conflicts of interests that might arise from such activities.

It does however have regulatory control of industrial safety in BNIs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** (1) GS-R-1 §3.1 states *"In order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions.* (2) GS-R-1 Section 3.2 (1) states. *In fulfilling its statutory obligations, the regulatory body shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;* (3) GS-R-1 Section 3.3(9) states *"the regulatory body shall ensure that its regulatory principles and criteria are adequate and valid, and shall take into consideration internationally endorsed standards and recommendations;"*

R5 **Recommendation**: ASN has many orders and guides under review and in preparation to further incorporate IAEA standards and WENRA reference levels. This work should be completed as soon as practical as part of the renovation of the French nuclear and radiation safety regulation. This should also create a single, comprehensive set of orders and guidance that are clear and useful to all parties involved.

(1) **BASIS:** GS-R-1 §3.3(5) states *"the regulatory body shall provide an explanation of the reasons for the rejection of a submission"*

G3 **Good Practice:** Reasons for the rejection of a submission are given not only in ASN decision letters, but also are published on the ASN web site.

(1) **BASIS:** GS-R-1 §3.3(7) states *"the regulatory body shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated;*

R6 **Recommendation:** ASN should initiate and make arrangements to improve the timely reporting of occupational radiation exposure doses for oversight and analysis of radiation protection practices. [Dose information should be made available in a timely manner to individual employees and employers and ASN to help ensure optimization and limitation of radiation exposures].

3. ORGANIZATION OF THE REGULATORY BODY

3.1. GENERAL ORGANIZATION

GS-R-1 § 4.1

As the Law n°2006-386 of 13 June 2006 came into force on 9 November 2006 and the Commission met for the first time on Monday 13 November, the ASN is now organized as described below. (See also Appendix IX for an organigram).

The Chairman of the Commission heads the ASN; the Director General is responsible for the day-to-day management of the ASN. The Chairman and two Commissioners are appointed by the President of the Republic, one Commissioner is appointed by the President of the senate and one is appointed by the President of the National Assembly; the ASN reports only to the parliament. This situation ensures an effective independence from any governmental structure charged with the promotion of nuclear energy or depending on any use of ionizing radiation.

The ASN is divided into seven divisions ("sous-directions or SD") as follows:

SD1	Fuel cycle, radioactive sources and transport
SD2	Power reactors
SD3	Research BNI, decommissioning, waste
SD4	Inspection, training, emergency situations and environmental protection
SD5	Under pressure equipment
SD6	International relations
SD7	Ionizing radiation and Health (Health and medical uses, Radon, Norm, drinking water)

The ASN also has staff in 11 regions where one division for Nuclear Safety and Radiological Protection (DSNR) is embedded in its respective DRIRE (Regional Directorates for Risk Industry and Environmental Protection) located in Bordeaux, Caen, Chalons-en-Champagne, Douai, Dijon, Lyon, Marseille, Nantes, Orléans, Paris et Strasbourg.

SD5 (also called BCCN: Control Bureau of Nuclear Pressure Vessels) is located in Dijon with the DSNR, and the DSNR of Paris is responsible for the inspection in the DOM-TOM (Overseas Territories and Départmentes).

A legal and organization section supports the Commission, the DG and the Deputy-DGs in the management of the ASN through the coordination of action and organising the periodic meeting.

Another section called Secrétariat général – SG – is responsible for the management of the resources (human resources and budget); this section is also in charge of the communication and public information.

To check compliance with the GS-R-1 requirements, the team examined successively the following items: budget, staffing, training, technical support organization, advisory bodies, relations with the operators and international relations.

Budget

The budget of the ASN is a part of the general budget of the French State: it is the Action 3: *Nuclear safety and radiological protection* of Programme 1.27 *Risk supervision* in the mission *Economic and development regulation*. It is established according on the general rules of the

French Civil Service (LOLF) and is based on indicators which determine directly the amount of money for the next year. The performance indicators are the following:

- Number of accidents
- Number of inspections
- Delays to publish the decisions of the ASN
- Measures of the recognition and profile of the ASN
- Number of press releases

To carry out this assessment ASN has developed since 2005 a "barometer" as a means for assessing trends using the performance indicators to indicate whether the budget needs to be increased, decreased or maintained at the same level. The use of such a dynamic tool seems to have considerable merit, and could be adapted by other regulatory bodies.

It is noted that the ASN budget is subject to the same limitations as other French administrations, i.e. the replacement of half of the retirees of each year. But related to its relatively small size and the age distribution within the ASN, these restrictions seem to have a very limited impact.

3.2. STAFFING AND TRAINING

Staffing

(GS-R-1 §4.6)

In 2002, the former DSIN was turned into DGSNR and its responsibilities were extended to include radiation protection, formerly under the supervision of the Ministry of Health and Ministry of Labour. To cover this additional mission, approximately 20 new positions have been created each year since 2003, and this will continue for several more years. There has been an increase in the number of persons employed by ASN from about 200 at the end of 2002 to about 400 at the end of this year.

The new structure of ASN (Commission) will have an impact on the number of persons needed.

The mission concluded that the existing staff numbers seem to be in keeping with the actual missions of the ASN, but noting that this doesn't exclude some shortages in some specific areas (there are some indications in this respect for SD2 and SD5).

The "turn-over" can be identified as a likely source for some possible shortages. More than 50% of the personnel of the ASN are civil servants, belonging to the technical body of engineers (*Corps des ingénieurs*). According to the normal rules of the French civil service, they have to stay at least 3 years in the same position before they may use their right to move to another position somewhere in the French civil service. Due to the long period of training within the ASN, typically taking a civil servant at least one year to become fully operational, ASN already recommends that staff stay at least 4 years before moving to another position.

Training

(GS-R-1 §4.7)

The training programme for "newcomers" seems to be very mature and developed.

- A first module includes topics of common knowledge such as emergency preparedness, media training or events assessment and some specific training dedicated to particular areas such as fuel cycle, decommissioning, radiological protection, and waste management.
- The necessary capabilities are classified into
    - common capabilities for each person in ASN;

- capabilities for nuclear safety on the one hand and radiological protection on the other;
- capabilities dedicated to specific activities, such as transport, nuclear reactors, medical applications, etc.;
- very specific capabilities related to the function of an individual position.

- It takes 12 to 15 weeks of training to become an inspector (NB. An inspector is not expected to cover all specific areas but is to choose a selection of them in accordance with the needs of his (her) functions, determined in close cooperation with senior staff).
- A second module of complementary training is specifically dedicated to inspectors; it aims to develop skills in some specific areas, such as criticality, NDT and equipment under pressure. Each person trains about 10 days each year; after a mean period of 5 years, an inspector can be accredited as a senior inspector after examination by a special committee.
- A tutor is in charge of helping each new person beginning to work in the ASN.

3.3. ADVISORY BODIES AND RESEARCH ORGANIZATIONS

Technical support organization (TSO)

(GS-R-1 § 4.3)

In some countries, regulatory bodies are rather large and are self sufficient in technical staff. In other countries, regulatory bodies may be relatively small but they are technically supported by other organizations (TSO). Such a difference is not a problem if all the regulatory decisions are made independently, based on sound technical knowledge.

In the case of France, ASN, the regulator, is strongly supported by IRSN, which is not only a TSO but also a research institute.

Article 1 of the Decree n° 2002-254 of 22 February 2002 concerning the Institute for Radiation Protection and Nuclear Safety states:

> *"The Institute for Radiation Protection and Nuclear Safety, a public State institution of an industrial and commercial nature, performs functions of expertise and research in the following areas, to the exclusion of all and any responsibility as a nuclear operator:*
>
> *a) Nuclear safety;*
>
> *b) Safe transport of radioactive and fissile materials;*
>
> *c) The protection of man and the environment against ionizing radiation;*
>
> *d) The protection and control of nuclear materials;*
>
> *e) The protection of nuclear installations and transport of radioactive and fissile materials against malicious acts".*

The team's findings with respect to the relationship between ASN and IRSN are as follows[♦]:

- The IRSN, as a public State institution, is placed under the joint authority of the Ministers responsible for Defence, Environment, Health, Industry and Research. IRSN employs about 1650 persons, 1000 of whom are graduates.
- The relations between ASN and IRSN are, in the first instance, dominated by a Charter.
- The relations between ASN and IRSN are regulated by a special agreement (Convention) covering a period of 3 years, and determining the main themes of the following annual plans.

♦ A more detailed note about the role and the position of IRSN is given in Appendix IV

- Each year, the annual plan is established and run through a comprehensive process involving both partners: preparatory meetings in advance and follow-up meetings on a regular basis during the current year. This plan contains a detailed description of the work that ASN will ask IRSN to do.
- Each demand from ASN to IRSN for assessment contains a detailed description of the scope and a clear milestone for finalizing the report.
- The IRSN role as a TSO is supported by IRSN itself as a research institute. IRSN maintains a high level of technology by promoting research, and this reflects on the capabilities needed as a TSO.
- On the other hand, as usually seen in research institutes, IRSN is offering its technology not only to the regulator but also to industry, including licensees such as EDF and AREVA. However, IRSN has no technical support contracts with licensees, or even with nuclear operators abroad.
- It should be kept in mind that good communication between research institutes and industry organizations is always necessary. Without knowledge about the actual plants or the real behaviour of operators, vendors and manufacturers, safety research will yield very poor results. A typical example is a research on the integrity of high burn-up fuel under accidental conditions. Such research is only possible with the use of high burn-up fuel provided by an operator.
- To maintain independence in regulatory decision-making, there seem to be "firewalls" established within IRSN. The experts in charge of regulatory support to ASN are not the same as the experts in charge of the support to the industry.

As a result from the visit to IRSN, the team considered that the following items need to receive some attention:

- a more active ASN role in the specification of future research tasks covered by IRSN should be encouraged;
- more support from ASN is expected for activities related to safety assessment of future reactor designs;
- some formalization of safety assessment criteria, analysis and assessment procedures would enhance control and independent evaluation of IRSN work.

Advisory Bodies

GS-R-1 §4.9

Standing Groups (*Groupes permanentes – GP*): These are set up by the Decision of 27 March 1973; there are four standing groups dedicated to:

- Nuclear power reactors;
- Other basis nuclear installations (BNI);
- Long-term management of radioactive waste;
- Transport of radioactive and fissile material.

A fifth group to be devoted to radiological protection is currently under review.

Experts coming from different backgrounds (including licensees) take part in the discussions. The meetings are briefed by submissions of reports generally written by IRSN on request from ASN.

The Power Reactor group (*GP Réacteurs*) is the most active and meets at least each month. Some of these meetings take place within an authorization process and the advice of the GP is considered as a formal stage of the process.

Inter-ministerial Commission for the Nuclear Basic Installations (*Commission interministérielle des INB - CIINB*): This Commission was set up by article 7 of Decree n°63-1228 and its role is defined in article 8:

> "The *Commission gives its opinion on applications for authorization decrees or modification permits for basic nuclear installations and on the specific articles and conditions applicable to each installation. The Commission advises and makes proposals on other questions concerning basic nuclear installations and notably: - the drafting and implementation of the regulations governing these installations and notably the general requirements to be complied with to avoid the dangers or drawbacks which could be occasioned by the construction or operation of these facilities. In this capacity, the Commission reviews draft texts regulating the protection of workers, the public, nature and the environment when basic nuclear installations are concerned*."

According to the new TSN 2006 Act, this commission will be replaced by a new Consultative Commission whose composition, mission and manner of work will be quite similar.

Central Commission for Equipment under Pressure (*Commission centrale des appareils à pression - CCAP*): A specialized section of this Commission gives advice to the ASN (and more specifically to SD5 (BCCN)) on the design, the construction and the control of vessels and pipes under pressure. SD5 prepares the files submitted to the Commission.

French Agency for Environmental Health Safety (*Agence française de la sécurité sanitaire de l'environnement et du travail – AFSSET*): This Agency is the focal point for the expertise and the dissemination of information about the health aspects of the working place and/or of the environment. Its last advice relates to the presence of *Legionella* in cooling towers.

French High Council for Nuclear Safety and Information (*Haut conseil de la sûreté nucléaire et de l'information*): Although some persons of the ASN should take part in the work of this High Council, it is not considered as an advisory body to the ASN. Furthermore, it will be replaced by *the High Committee for Transparency and Information on Nuclear Security* in the framework of the new TSN 2006 Act.

3.4 INTERFACES AND LIAISON WITH LICENSEE(S) AND OTHER ORGANIZATIONS

Relations with the operators

(GS-R-1 §4.10)

ASN aims at an open and frank relationship with the operators. In addition to professional regulatory contacts (e.g. inspections, topical licensing issues), ASN meets the operators periodically. DSNR meets each operator at the site level, while the DGSNR meets the operators at the national level. There are no formal agreements in place for the relationships or the meetings, but the practical arrangements have been working well.

Due to the long tradition of the public sector ownership of NPPs, the regulator has known the licensee (EDF) well and relationships with the licensee and the operators have been traditionally good.

3.5 INTERNATIONAL CO-OPERATION

GS-R-1 §4.11

ASN has relations on a regular basis with the International Atomic Energy Agency (IAEA), participating at the meetings of the parties of the different Conventions, and dealing with a very

large spectrum of activities including membership and representation at various committees (CSS, NUSSC, RASSC, TRANSC and WASSC).

ASN is also an active member of the standing committees (and their working groups) of the OECD's Nuclear Energy Agency (NEA). Some representatives of the ASN contribute to the work of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

ASN is also a major player in the various activities initiated by the European Union, through the European Commission's working groups related to the "Nuclear action plan" and the assistance to the Eastern European countries.

Finally, ASN is an active player in the different Associations of Nuclear Regulators (INRA, WENRA and FRAREG).

ASN has also developed extended bilateral agreements with neighbouring countries as well as other interested ones, such as Japan, Argentina and the USA. These bilateral agreements include exchange of information related to nuclear safety and radiological protection, joint undertakings in the development of harmonized European regulations concerning geological disposal of radioactive waste, joint inspections and mutual exchange of inspectors.

A well-staffed section supports the actions of ASN in international affairs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §4.6 states: "*The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions."*

R7 **Recommendation**: To avoid too fast a turn-over leading to too many people leaving the ASN after a short period, ASN should organize and foster more possibilities for rotation of positions within ASN.

(1) **BASIS:** GS-R-1 §4.7 states: *"In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff is aware of technological developments and new safety principles and concepts."*

G4 **Good Practice:** The training programme is mature and well developed.

(1) **BASIS:** GS-R-1 §4.11 states: *"The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighboring States and other interested States, and with relevant intergovernmental organizations, both to fulfill safety obligations and to promote co-operation."*

G5 **Good Practice:** The involvement of ASN in the framework of international cooperation is quite active and exhaustive and bilateral agreements are well developed.

4. ACTIVITIES OF THE REGULATORY BODY

4.1 AUTHORIZATION

This section reviews authorization of each of nuclear power plants, research reactors, fuel cycle facilities, medical practices, industrial and research practices and waste facilities, using the requirements of GS-R-1, listed here, as the basis. The text references GS-R-1 as applicable.

GS-R-1 §5.3 – 5.6

4.1.1. NUCLEAR POWER PLANTS

GS-R-1 §5.1

TYPES OF AUTHORIZATION

Nuclear power plants (NPP) belong to Basic Nuclear Installations (BNI) together with other nuclear reactors, particle accelerators, fuel cycle facilities, and installations for use, treatment and storage of radioactive substances, including radioactive waste. Authorization of all BNIs is processed in the same way, with some differences according to the level of risk and complexity of the installation. Among about 140 BNIs in France, there are 58 Pressurized Water Reactors (PWRs), which are in operation on 19 sites (34 reactors 900 MWe, 20 reactors 1300 MWe, 4 reactors 1450 MWe). Types of authorizations issued by the ASN in connection with a NPP are shown in the table below.

Type of authorization	Format of authorization	Approving official
Creation of a new BNI	Decree	Prime Minister
Authorization of effluents and water intake	Ministerial order	Ministers of Industry, Environment and Health
General Operating Rules (GORs)	Letter of approval	Head of ASN (by delegation)
Authorization of modifications	Letter of approval for small modifications or a Decree for large modifications (with an impact on conditions for creation of a BNI)	Head of ASN or Prime Minister
Authorizations for restart after outages	Letter of approval, or internal authorization	Head of ASN, or his Directors; by delegation, or the licensee
Authorization of environmental protection installations	Letter of approval	Head of ASN
Authorization of new fuel or of new fuel management scheme	Letter of authorization	Head of ASN

In accordance with the previous legislation, authorizations were formally approved by members of the Government (Ministers), although the majority of them were delegated to the head of ASN. In the future, all the authorizations except creation of a new NPP will be the responsibility of ASN,

and the Ministers will only formally approve the ASN authorization (which is necessary because of the French constitution).

Due to the number of power reactors the total number of authorizations issued each year is quite high. Nevertheless, the number of authorizations does not rise proportionally with the number of reactors, since, due to the high level of standardization, modifications are introduced through authorizations for reactor types rather than for individual reactors. The majority of the authorizations are devoted to NPP modifications. ASN deals yearly with approximately 100 authorizations of modifications, of which approximately 70 % are for modifications of General Operating Rules and 30 % are for modifications of hardware.

Authorization of all matters related to NPPs is mainly managed by the ASN sub-directorate SD2, in cooperation with SD5, which is responsible for pressure vessels. SD2 has responsibility for both pressurized water reactors in operation as well as authorization of new reactors (EPR is currently under review). Decommissioning of reactors is covered by sub-directorate SD3, which also has responsibility for research reactors and for fast reactors.

SD2 employs more than 30 staff, who are involved both in development of regulations and in preparing authorizations. The staff are partially also involved in inspections, although most inspections are conducted by regional entities of ASN. SD2 and SD5 communicate directly with the associated regional offices and also at a high level with the central service of EDF. Communication of SD2 with each specific BNI is arranged through the ASN regional office.

SD2 is subdivided into 4 technical sections: fuel and operating; environment and hazards; systems; and regulations and authorizations for new reactors. The Fuel Section also has responsibility for accident analysis and issues related to emergency operating procedures (EOPs). Each of the sections employs 6-7 engineers. The organization of work of SD2 is done in a matrix manner, meaning that for some specific and important tasks there may be involvement of staff from several sections. Such groups are established for: General Operating Rules, Experience Feedback and Event Analysis, and Local Support for Regional Entities and quality.

GS-R-1 §5.3

Basic rules for the process of authorization are described in the internal ASN note on ‘Authorizations’. The note specifies relevant legislative acts, responsibilities of ASN organizational units, general principles of authorizations and rules for archiving the documents. Other ASN notes, namely on ‘ASN General Organization’ and ‘Delegation of Signature’ also apply.

GS-R-1 §5.4

Formal application comes to ASN with a letter from EDF (currently the only licensee for NPPs), and is usually for multiple modifications, with a reference to the previously established modification and review plan. The letter includes all supporting documents. In the case of modifications, the first letter from EDF also includes a proposal for classification of the modifications according to their safety impact. This proposal is evaluated and re-classified, if necessary, by ASN. Approximately 3 months after the classifications, ASN receives a file with all justifications.

The Senior Management Board of ASN defines the ASN organization for examination of individual applications. An application review is performed in 2 steps: checking of the acceptability of the submission for completeness, and the technical examination. The ASN conclusion of the acceptability check may be written in a formal document. Depending on the nature of the application, other administrations, the technical support organization and the public can be involved in the examination. The examination may also involve on-site visits or inspections.

Formally, the authorizations can be managed either by ASN directly (external authorizations) or the rights for issuing the authorizations can be handed over to the licensee (internal authorizations). Internal authorizations are described below.

Generally, technical examinations required for authorizations are strongly supported by IRSN, the technical support organization. Both classification and justification may be assessed by IRSN upon request. In addition, services of standing groups of independent experts (including international experts) are available for 4 different subject areas: nuclear reactors, transport, waste, and laboratories and facilities. Experts from various institutions are involved in the standing groups, including IRSN, ASN, operators, universities, and EDF (the licensee). Standing expert groups receive from ASN a preliminary programme of activities for the next 3 years with a detailed list of topics to be evaluated. IRSN prepares the report for every meeting of standing groups. This mechanism allows for very good planning and organization of work for both ASN and IRSN. ASN has a good overview of expected future activities, since it shares a relevant database with EDF which is updated every 3 months. One such database includes hardware modifications while another one includes modifications of GORs.

A number of legally binding documents are used as a basis for the examinations. The basic set of reference documents consists of 6 decrees or codes, and 11 orders. There are 24 different Basic Safety Rules (not legally binding) on various technical issues available as reference documents for technical examinations of PWRs. In addition, there are many ASN letters, notes and guides concerning various individual authorizations.

GS-R-1 §5.5

Following the examination, the decision is taken in two steps: elaboration of the draft decision by the examining entity and the decision itself made by an assigned person in accordance with the rules for signatures. The decision is issued either as a decree or as a letter of approval depending on the subject. The licensee may be asked for his opinion prior to the decision. The decision can be approval, approval with conditions, or rejection. The decisions made by ASN are mainly based on expertise and not so strictly on comparison with the codes and standards. Individual authorizations may be released to the public either because it is required by regulations or as a result of an ASN decision.

The basis for rejection of an application can be non-compliance with legally binding documents, non-compliance with the basic safety rules or with some kind of qualitative requirements, or due to uncertainty in methodology and resulting small safety margins. An example of rejection of an application for a specific case was related to a major change in the use of MOX fuel (enrichment and burn-up increase). The letter of rejection contained 13 pages of evaluation from various points of view. Rejections are typically explained in more detail than approvals because of the possibility of appeal.

The whole process of authorizations is adequately documented in accordance with the ‘information management’ of the ASN documentation system. The status of documents for all relevant applications is maintained in a database and updated electronically. The database includes the nature of the application and expected milestones in preparing the authorization. The current status of the authorization is regularly updated. ASN has an internal system for checking timeliness of authorizations, which is also used as one of their performance indicators. Internal evaluation and justification is recorded and archived if it is believed that there is an added value, and it is explained in written form if not completely clear from the final authorization letter. This mechanism could be formalized and improved in order to provide for future use of the information collected during authorization.

ASN has no formally legally binding fixed time limits for issuing authorizations (although other state administrations do). Therefore, authorization reviews may last from a few months for simple

modifications up to many years for creation of a new NPP or for modification of a fuel management scheme. The only time limit is a five year validity for a public inquiry in the case of a creation decree. If the decree is not published within five years the inquiry is required to be repeated.

Time limits for processing the authorization applications are set internally, but the limits are not always successfully maintained. In special cases, the Senior Management Board may stipulate time limits. In spite of the absence of time limits, ASN intends to improve the timeliness of the authorization process by simplifying it and by more efficient project management. Information flow management and reporting can be improved. A shared information system is being implemented to aid this.

ASN does not directly issue licences to NPP subcontractors, but has full access to manufacturers of components in order to inspect their production from the design through manufacturing. In the past when such access was not ensured, the supply of a component to the NPP was sometimes rejected. ASN does not issue authorizations/certificates to NPP personnel. Instead, the operators receive their authority to operate the reactor from the utility. During inspections, ASN inspectors verify the satisfactory completion of the training of operators. The composition of operating staff in BNIs, and their responsibilities and qualifications are described in Chapter I of the General Operating Rules. The training programme for the staff is specified in internal procedures of the licensee which are inspected by ASN.

Until now, many authorizations were managed through letters. With progressive globalization and the possibility of a larger number of licensees, it would be appropriate to put these matters into regulations or guidelines. The improvements should be mainly focused towards formalization of already established processes. Existing plans call for broader utilization of IAEA Safety Standards in these improvements.

Different types of authorization related to NPPs will be described in more detail later in this section of the IRRS report. Authorizations for effluents and water intakes are discussed in a separate section.

AUTHORIZATION OF A NEW BNI

GS-R-1 §5.1

The main legislative document describing the process of authorization of a new BNI is Decree No. 63-1228 of December 11th, 1963. The process of authorization is very complex and consists of many steps. Prior to formal submission to the Government, it is mandatory to organize a public debate in accordance with the general environment law applicable for all big industrial projects. The public debate is organized under the authority of the Inter-ministerial Commission for Basic Nuclear Installations (CIINB). The report from the debate is a public document, which is used as advice to the Government. After receiving the report from the debate, the applicant has three weeks to decide whether to submit an official application to the Government.

GS-R-1 §5.3, 5.4 and 5.5

The authorization procedure is illustrated in the figure below. The application is sent to the Government by a letter accompanied by several documents required for the public inquiry. In parallel a Preliminary Safety Analysis Report (PSAR) is sent to ASN. The PSAR is reviewed by ASN while other documents are reviewed under the authority of Prefect in a public inquiry. ASN has no specific time limit for the examination. The same documents submitted to the Prefect are also sent to all other pertinent Ministers for their review. The resulting three reports produced in three parallel lines of this part of the authorization process are collected by ASN, who prepares a draft decree summing up results of the whole procedure. The draft decree and all the reports are then reviewed by the CIINB, and afterwards all documents are submitted to the Minister of Health

who has three months to reach a decision. If the Minister of Health reaches a positive decision, the authorization decree is signed by the Prime Minister. The decree authorizes

- The BNI (this is its approval from a nuclear safety point of view)
- Facilities of the BNI affecting the environment
- Use of radiation sources within the BNI.

This authorization process is conducted in parallel with a separate procedure for a construction permit which is fully under the authority of the Prefect.

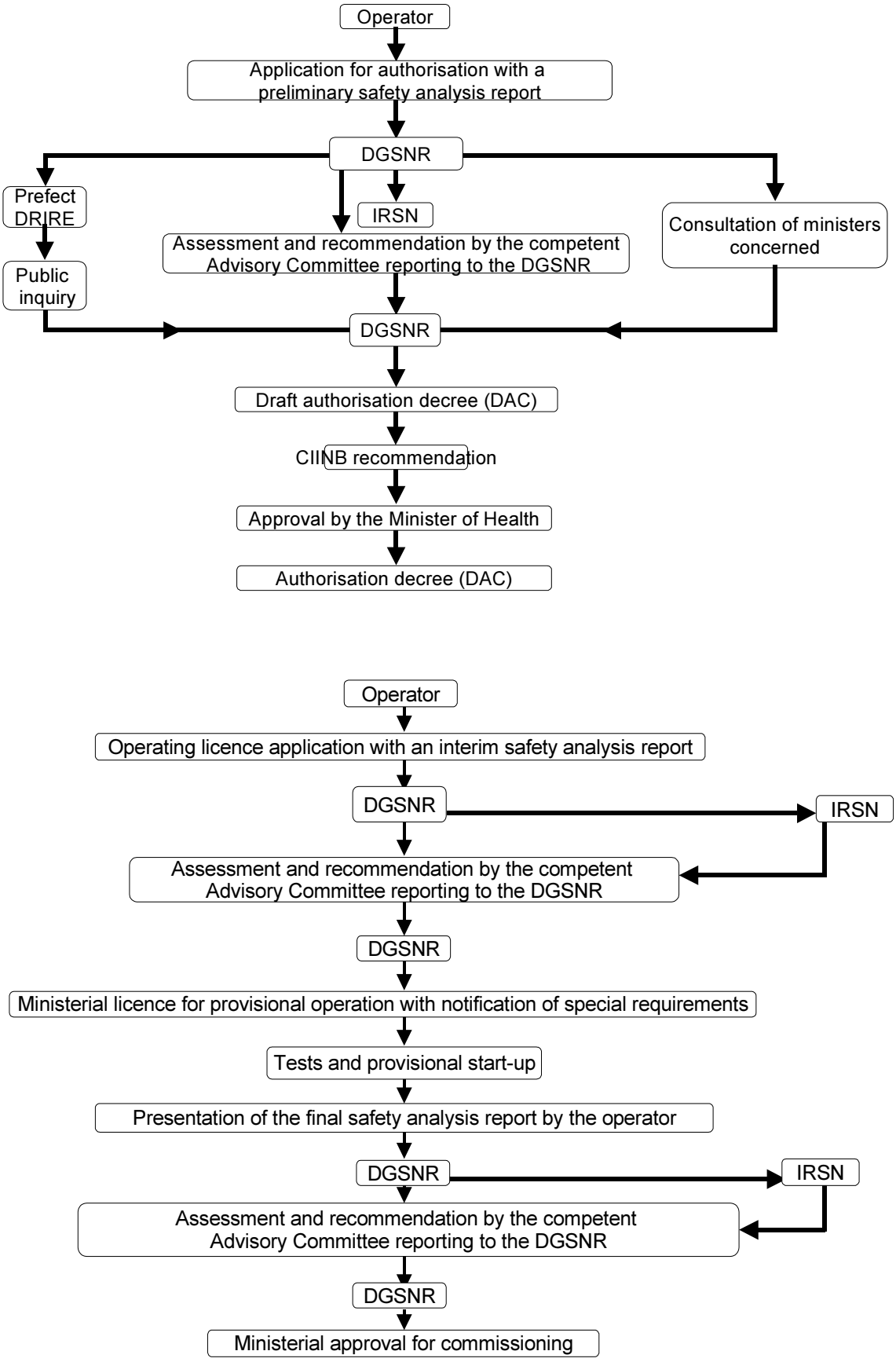
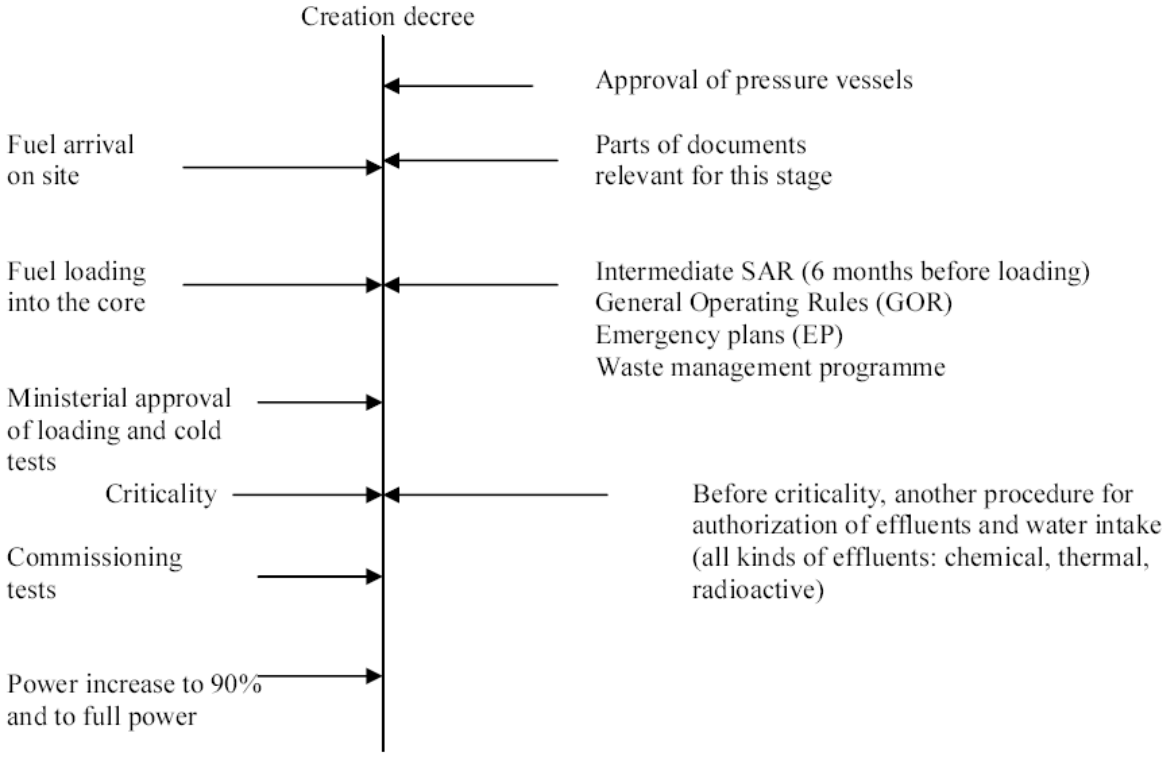


Figure: Authorization procedure for basic nuclear installations

The Prime Minister's decree also specifies the detailed conditions for creation of the BNI as well as the next stage of licensing and all documents that are to be prepared. The order and timing of subsequent approvals is shown below.



Several years after an NPP reaches full power (typically 2-3 years), the licensee is required to update the FSAR with operational experience feedback, at which point a final authorization for operation of the NPP can be issued. There is no specified time limit associated with the authorization. At present there is only one licensee operating NPPs in France (EDF), but there are no prohibitions on who may apply. Therefore, the number of licensees could increase in the future.

All explanations regarding the authorization process were supported by provided documents. As an example, the creation decree (license) for NPP Civeaux was presented and reviewed by the IRRS team. It was clear from this example that the creation decree was not just a simple approval letter, but was a comprehensive technical document containing more than 10 pages of conditions for further licensing steps and for future operation of the NPP.

AUTHORIZATION OF THE EUROPEAN PRESSURIZED REACTOR (EPR)

The licensing process for the new EPR reactor in France was presented to the IRRS mission as another example. This project was considered a special case from both the EDF and ASN perspectives. In particular EDF wanted to be reasonably sure in advance (prior to the formal authorization procedure) that the EPR is acceptable from a safety point of view. In fact, the process of formulating requirements for future NPP designs started before the EPR design was finalized. The whole process has already taken 17 years with the milestones as follows:

1989	political decision to launch the project
1993	German and French authorities set-up safety objectives
1997	Basic Design Report (a kind of generic SAR)

1999	Optimized Basic Design Report and Technical Guidelines for next generation of reactors
2004	A draft version of the PSAR received in January 2004; unofficial pre-certification review by ASN, without a corresponding final decision
2005-February 2006	Public debate
May 2006	Official EDF application for an authorization decree for EPR Flamanville
End of 2006	ASN assessment completed.

Different assessments of the design were submitted by EDF to ASN during the period from 1999 to September 2006. The detailed design review started in 2001, and 9 meetings of the standing expert group for nuclear reactors were held between 2002 and 2006. Currently, ASN is at the stage of drafting a creation decree. The Commission to review the decree was scheduled to deliberate at the end of 2006 or at the beginning of 2007. Following the Commission's recommendation and approvals by the Minister of Health and the Prime Minister, construction of the plant could start in 2007. Construction is anticipated to last approximately 5 years and operation of the plant is scheduled for 2012.

For the EPR, technical guidelines previously developed by German and French experts were established as official guidance for design by a ministerial letter. Although the guidelines were not issued as a formal regulatory document, they have de-facto the same power. The guidelines also included new design features required by IAEA Safety Standards NS-R-1 such as management of severe accidents, consideration of PSA and human factors.

A set of documents regarding authorization of the EPR was presented to the IRRS team. This set included letters asking for expert examination, various reports by groups of experts, decisions by ASN, letters to EDF and responses from EDF. Recommendations were made by the Standing Committee with many experts from Switzerland, Finland, Belgium, Germany and France involved.

Based on the positive experience gained during authorization of the EPR, ASN plans to formally establish a similar pre-certification process for generic designs, independent of the site. It may be appropriate to establish such a process early enough for future reactors, including Generation IV reactors. The pre-certification should be legally set-up in a new decree.

AUTHORIZATION OF MODIFICATIONS

GS-R-1 §5.3, 5.4 and 5.5

In accordance with Decree No. 63-1228 and the Ministerial order of 10th August 1984 on QA, all modifications (hardware, software or procedures affecting the documents associated with the creation decree of a BNI such as SAR, GOR, EP or waste management programme) must be authorized by the ASN. In order to optimize the process of authorization in accordance with the level of impact on safety, modifications are classified into 3 groups with different scopes of safety demonstration required from the licensee and different approval processes by ASN. Detailed information including risk analysis, human factor analysis, modification of the SAR and GOR, radiation protection impact and evaluation of feedback from previous modifications is required for all modifications with significant safety impact. Classification of modifications was explained in an ASN letter to EDF (dated 6th May 2002), describing how to classify modifications and what kind of documents are to be provided. The letter also contains a time schedule for submissions and the corresponding quality requirements. The modification classification is first proposed by EDF, usually reviewed by IRSN and finally agreed to or rejected by ASN. Although in the majority of

cases ASN follows IRSN advice, the final decision can differ. One case was presented to the IRRS team where the final decision was different from both EDF and IRSN recommendations. The ASN decision was supported by written justification. Similarly, the statement/recommendation of IRSN was comprehensively documented. Typically ASN manages several tens of modifications per year.

The milestones for planning NPP modifications are typically related to periodic safety reviews (PSRs), since according to the legal requirements one of the objectives for a PSR is to increase the safety level. During the PSR a comparison with current requirements is made by the experts. This process provides for effective long-term planning of authorization of modifications. Every year ASN receives a file from EDF regarding all modifications planned for the next year so that ASN can be prepared including availability of TSO support. Recently, the 3rd PSR for 900 MW reactors was performed, and led to approximately 30 modifications for this group of reactors. This year, classification of modifications for 1300 MW reactors following their first 10 years of operation will be performed. However, since PSR is the primary tool for the identification and specification of modifications, it seems appropriate to check whether the PSR is comprehensive enough to ensure that some important issues are covered adequately.

Time for implementation of a modification can take up to several years. Standing expert groups are extensively involved in the evaluation of proposed modifications. For example, for safety upgrading of 900 MW reactors, there were 8 meetings of standing expert groups to discuss the proposed modifications.

Given that there currently exists a high level of standardization in NPPs, and in order to maintain a high level of standardization, implementation of the same modifications for a given group of reactors is usually proposed, although there can be specific requirements or modifications for individual reactors. Also, currently having only one NPP licensee allows for communication between ASN and EDF by means of letters; this is not considered desirable for the future, and more formal regulatory documents and guidance should be developed.

Authorization of software is a specific case of authorization of modifications. As with other NPP modifications, three categories are recognized according to their impact on safety. Basic Safety Rule RFS II-4-1-a, May 2000 edition, applies for safety classified electrical system software as a reference document for assessment, together with the ASN letter of May 2002 defining the examination process for safety related NPP modifications and the NPP safety analysis report. Due to the complexity of software modifications, many organizations are involved (see the figure) and due to difficulties in justifying the quality of the product it may take 36-38 months to implement a modification. It is considered desirable to develop more general basic safety rules which will describe the process of authorization in more detail.

Changes related to nuclear fuel represent another specific case for modifications. Due to the importance of this type of modification it is described separately in the next section.

In general, high attention is paid by ASN to monitoring the implementation of modifications. This includes monitoring of the quality of design, quality of implementation and associated experience feedback.

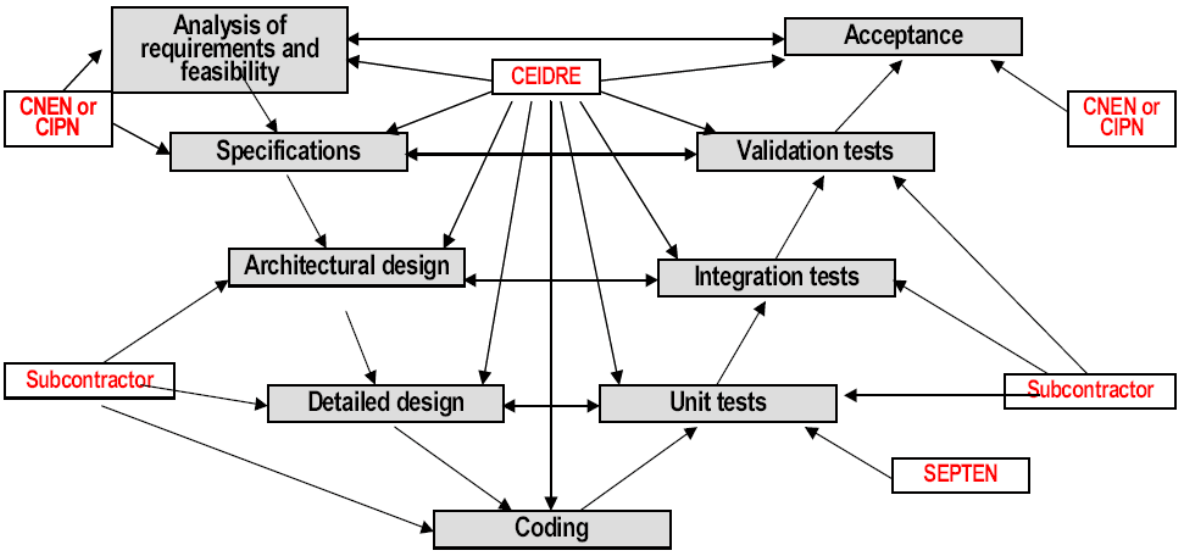


Figure: Process of authorization of safety related software

AUTHORIZATION OF GENERAL OPERATING RULES

GS-R-1 §5.3, 5.4 and 5.5

General Operating Rules (GOR) together with the SAR, EP and waste management programme are the most important documents associated with the creation decree of any BNI. GORs complement the information contained in the SAR, and they contain all the provisions to be implemented in the operation of NPPs in order to ensure the plant's operation in accordance with the plant safety analysis. GORs are a generic document, valid for a group of reactors of the same type, and they serve as a basis to be followed in development of the specific plant procedures. In accordance with Decree No. 63-1228 of 1963, any change of the GOR is to be approved by ASN. The GOR consists of the following chapters:

- 0 - Organization for updating of plant documents;
- I – Operating organization of the plant
- II – Quality Assurance;
- III – Technical Operating Specifications (STE);
- IV – Management of radiation protection;
- V – Procedures for discharge of radioactive effluents;
- VI – Operating rules for incidents and accidents;
- VII – Internal emergency plan;
- VIII – Requirements for operating rules under normal operating conditions; and
- IX – Routine test and inspection programme for safety-related equipment; and
- X – Physical test programme for reactor core loads.

Chapters III, VI, IX, X and technical specifications for chemistry and radiochemistry are considered by ASN as the most important parts for approval by ASN. Chapter III of the GOR defines the normal operating limits of the facility in terms of the allowable range for operating parameters such as pressure, temperature and neutron flux, defines set-points for activation of the safety functions and specifies the course of actions to be followed in case of equipment unavailability. Chapter VI contains the technical basis to be reflected in EOPs. It introduces a state

based/symptom based approach for maintaining or recovering fundamental safety functions during incidents or accidents. Chapter IX prescribes rules for checking the availability of safety related equipment and for routine tests and inspection programmes. Rules for the programme of re-qualification of the core during the reactor restart and for core monitoring during operation are in Chapter X. Chemistry related technical specifications define parameters of the chemical regime and limits on corrosion/erosion of coolant circuits in order to ensure the integrity of barriers. Radiochemistry specifications define rules for monitoring parameters related to spectrometry, global coolant activity and content of tritium.

It can be seen from the list of contents of the GOR that this document deals not only with nuclear safety but with radiation protection aspects as well including occupational radiation protection. By maintaining strict control of GORs, radiation protection in NPPs is also effectively covered. There is also a special chapter in the SAR that discusses the radiation protection service and its obligations in a NPP. The required content is largely consistent with the requirements of the BSS and IAEA Safety Guide RS-G-1.1 on Occupational Radiation Protection. Implementation of required measures (such as establishment of the radiation protection service, establishment of control areas and adequate monitoring of areas and personal dosimeters) was verified during a visit of the IRRS team to the NPP de Nogent-sur-Seine.

Modifications of GORs typically originate during PSRs, but can also be imposed due to modifications of the fuel assembly design or the management system, due to modifications of plant equipment, due to implementation of operational experience feedback, or due to changes intended to improve plant economy. For any change of GOR chapter III, VI, IX or X, the licensee must submit relevant safety justification.

Since 1999, the licensee has introduced a consistent control of the operating documents configuration management (called the Palier technique documentaire (PTD) concept). This concept takes into account that all the documents are technically linked and must be consistent with the technical status of the plant (modifications of equipment, operating modes, new fuel management schemes). The PTD is based on the ten year PSR, or if needed, an intermediate PTD may take place after about five years (see the figure). The overall process of examination of an application and authorization is shown in the figure.

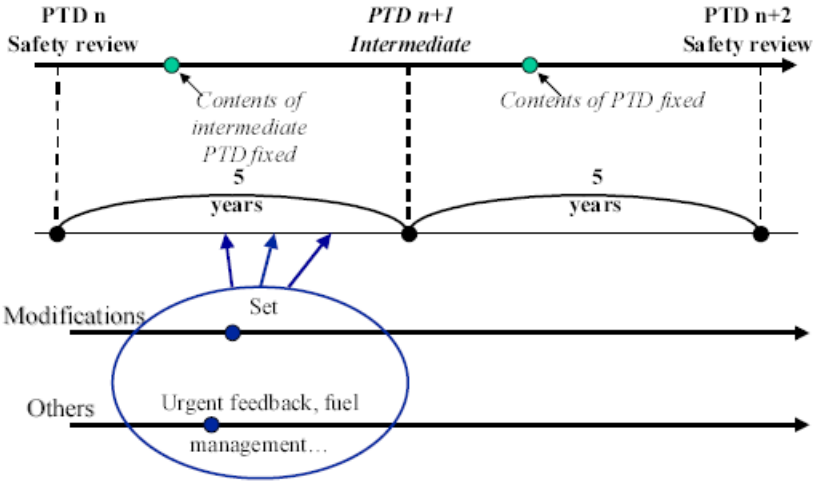
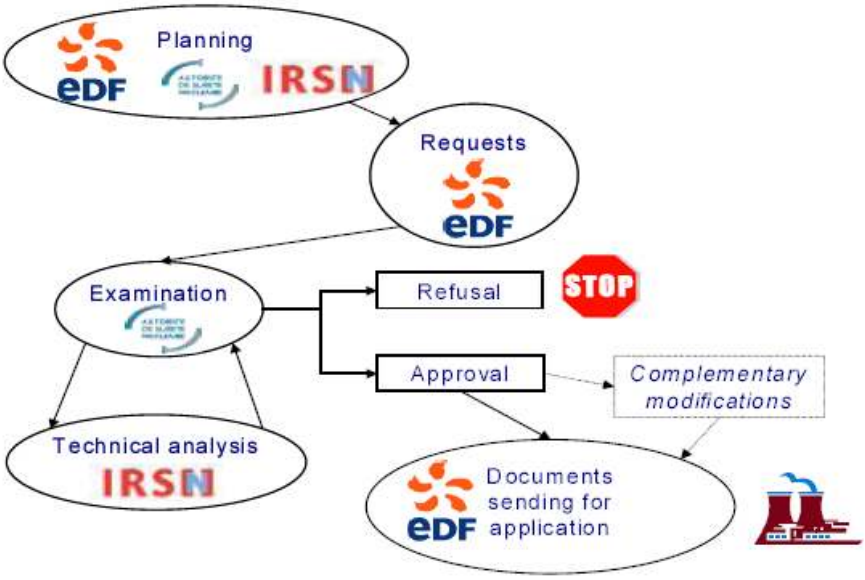


Figure: Use of PTD concept in authorization of General Operating Rules



In the examination, the central administration of ASN examines generic documents for a given group of reactors, while a regional office of ASN examines specific conditions on the site and the consistency of local conditions with the generic document. The TSO is extensively involved in the examination of the most important issues. The scope of examination to be performed by IRSN is specified by ASN. The examination is to assess whether there is any negative impact on safety and to verify that the safety improvement is adequate. A complete analysis must be presented. The process of authorization includes the prioritization of modifications. Regular meetings are held approximately twice per year between EDF, ASN and IRSN. Time for examination is not limited, but it is intended to be as short as possible in order to facilitate implementation of improvements as soon as possible. Estimated time for the authorization review has to be announced to the licensee. Modifications are planned three to five years ahead. Time for examination depends on the complexity of the issue and can be up to more than one year. The authorization is communicated to the licensee by a letter signed by delegation of Ministries of Industry and Environment to the Director General or Deputy Director General. In case of a need for exceptions

from the GORs, the licensee must send a waiver request to the ASN. After analysis of the case, ASN makes the decision whether the waiver can be accepted or not and specifies compensatory measures to be imposed if necessary. In 2005, there were 148 waivers authorized. Implementation of modifications and compliance with the GOR is verified by inspection. As a part of the WENRA harmonization process, new regulations and guidance are planned on procedures for approval of modifications to the GORs and of the contents of the GOR.

AUTHORIZATIONS RELATED TO FUEL

GS-R-1 §5.3, 5.4 and 5.5

Conducting irradiation tests in power reactors, adopting new fuels for the reactors, as well as changing the main characteristics of the operating cycle are considered to be plant modifications and require a formal authorization by the safety authority. The main expertise related to review of modifications/authorizations related to fuel resides in IRSN, although SD2 employs two fuel project inspectors.

There can be different cases of fuel authorizations with increasing level of complexity:

- Irradiation of limited number of fuel rods placed in a limited number of fuel assemblies;
- Irradiation of several fuel assemblies containing new type of fuel;
- Authorization of a complete batch of fuel assemblies;
- General use of new types of fuel assembly;
- Use of new materials for fuel assemblies; and
- Changes to the fuel management scheme (includes enrichment, burn-up, number of cycles, duration of the cycle).

Currently the procedure for authorization and other requirements are described in a letter from ASN to EDF, with the latest version being issued in September 2006. The letter also specifies the minimum scope of documents to be submitted. Acceptance criteria for fuel are proposed by the fuel designer and are specified in the SAR. ASN is considering publishing a regulation or formal guidance on fuel authorizations including acceptance criteria.

The procedure for authorization is different depending on the complexity of the modification. For less substantial modifications, less detailed information is required: description of the fuel, characteristics of irradiation, feedback from previous experience, safety demonstration in a limited scope (if parameters are covered by existing margins), etc. This simplified authorization process may take several months and must be renewed it the operator wants to extend the irradiation beyond the limits (e.g. burn up or number of operating cycles) provided in the authorization.

The application for adopting a new type of fuel is normally made in steps. The application is initially for one reactor followed later by an application for the whole reactor series. If the application is made for several reactors initially, possible adverse effects on the back end of the fuel cycle are to be taken into account. Generally, in order to adopt a new fuel for a set of similar reactors, the operator will have to submit a file showing:

- no excessive adverse effect on the fuel cycle installations (i.e. enrichment or reprocessing plant, transport, final waste storage),
- acceptable behaviour in reactor operation under normal, incidental and accidental conditions,
- good feedback from operating experience in reactors.

When the operator intends to change the initial enrichment, the duration of the cycle or the renewal fraction, it is considered by ASN that this is a change of the 'fuel management scheme', which implies a major safety evaluation. For that purpose, the operator shall submit successively:

- a feasibility file, and
- a safety file.

The feasibility file aims at demonstrating that there is no principal objection to the envisaged scheme (no reason for exclusion) and includes the following information:

- description of the fuel management scheme,
- feedback from experience on fuel behaviour, fuel handling, reactor operation,
- theoretical knowledge and experimental evidence of fuel behaviour,
- rules, methods and software to be used for the safety studies,
- descriptions of the equipment modifications and of the organization planned for implementing them.

The safety file aims at demonstrating the safety of the reactor operating with the new fuel management scheme and includes the following information:

- safety studies for accidental conditions;
- safety assessment of the equipment modifications;
- link between safety systems and accidental transient;
- updated version of the safety analysis report; and
- updated version of the general operating rules.

Specific problems may arise from using mixed cores with fuel from two different suppliers (e.g. Westinghouse and AREVA). The entire process of introducing a new fuel management scheme takes approximately three years and involves a hearing before the standing committee for the safety of reactors.

The process is illustrated in the following table (J0, J1, J2 are milestones in the authorization process):

Organization	Timing	Action
EDF	12 months prior to J0	Submission of the feasibility file with the prescribed content
ASN	J0	Position on the feasibility file regarding absence of excluding features
EDF	16 months prior to J1	Submission of the safety file
ASN	16 months prior to J1	Kickoff meeting of standing group of experts with identification of sensitive issues
ASN	13 months prior to J1	Position on completeness of the justification file
EDF	13 months prior to J1	Submission of updated GOR and SAR, including supporting studies

ASN	10 months prior to J1	Definition of items to be addressed by standing group of experts
ASN	4 months prior to J1	Meeting of standing group of experts
ASN	J1	Generic position on authorization of a new fuel management scheme
EDF	6 months prior to J2	Submission of conformity check between authorization file and real conditions for a given reactor
ASN	J2	Authorization for loading of fuel into a given reactor

The IRRS team concluded that fuel modifications were very carefully managed and authorized.

REACTOR OUTAGE CONTROL

GS-R-1 §5.3, 5.4 and 5.5

ASN controls up to 50 reactor outages of 3 different types per year:

- ASR – refuelling outage which typically lasts 30 days and includes ASN presence 4 – 5 days on site;
- VP – refuelling with maintenance outage lasting about 60 days with ASN presence approximately 10 days on site; and
- VD – 10 year outage for refuelling extended maintenance and testing of the plant, with duration about 120 days and ASN presence 15 – 20 days on site.

The legal basis for outage controls is the Decree 63-1228 and the Order of 10 August 1984 on Quality Assurance. Included in ASN inspections are previous decisions on technical issues and modifications specified for the outage, compliance with the GOR and the outage maintenance programme of the licensee. The process of outage control is also important as a source of experience feedback and identification of generic safety issues. An authorization for restart of the plant is delivered by ASN (or an internal authorization by the licensee, see the next section). At the central ASN level, SD2 and SD5 are involved in the outage control. At SD2, 30 project managers are working on generic issues (e.g. civil constructions, I&C) and 6 experts are on permanent duty to follow up outages. Similarly at SD5, 32 project managers work on generic issues (e.g. related to the primary circuit or secondary circuit) and 6 persons are on duty to follow the outages. In addition, regional inspectors are extensively involved in the outages. There is one inspector working for two reactors. The inspector visits the plant regularly, evaluates the outage programme, follows the outage activities, assesses the position on particular issues which arise, studies the outage summary, prepares the restart authorization and studies the restart tests. Technical support can be requested whenever needed. An Outage Control Checking Form has been developed and utilized as a means of tracking activities during the outage and as a communication tool between the regional entity and the central ASN. There are 4 forms used for ASR outage, 6-7 for VP outage and 10 for VD outage.

INTERNAL AUTHORIZATIONS

GS-R-1 §5.3, 5.4 and 5.5

In order to enhance the licensee's prime responsibility for safety and to have more human resources available for major applications, in December 2004 ASN introduced internal authorizations for selected activities. For such activities authorizations can be processed by the licensee under specific rules. Currently for NPPs, these authorizations are limited to two cases, a

restart after a short refuelling outage (i.e. refuelling without maintenance) and an approval of mid-loop operation. Following an operational event these two activities became subject to regulatory authorization upon request by ASN; this was done without an adequate legal basis, since it was not based on a ministerial decree. The authorizations were introduced by ASN in order to prevent recurrence of the operational event. It was later realized that the problem was adequately addressed by the plants and that the authorizations were no longer necessary. From this experience the licensee was asked to propose a procedure for internal authorizations which was accepted by ASN. The main conditions for acceptance of the internal authorization process were as follows:

- Formalization of the process and its conformance with the licensee's QA system
- Definition of relevant conditions by the Technical Specifications of the plant
- Examination of the authorization by the licensee according to the rules established by ASN, which in certain cases is by a committee independent of the group responsible for the activity concerned
- Establishment of independent supervision of the process by the licensee, including the system for identification of non-conformances (non-conformance management)
- Implementation of the process for updating by the licensee of all affected relevant safety related documents
- ASN notification of the internal authorization with sufficient information prior to implementation
- Periodic transmission to ASN of a summary of internal authorizations and the lessons learned.

In accordance with established rules, internal authorizations are under strict control of the EDF central services. The National Committee for Internal Authorizations (an internal EDF committee) makes the principal decisions on internal authorizations. The central service of EDF delivers an authorization to a NPP on a case by case basis by a formal letter. For some plants, selected by EDF based on their good performance, the EDF central service issues a permanent authorization to the plant, but for this case a local organization with an independent team responsible for safety oversight must be in place.

In the future EDF intends to include additional internal authorizations. Based on the existing experience, ASN is of the opinion that EDF is doing its job very seriously and responsibly. The right for ASN to check and inspect the process is fully ensured and ASN utilizes a special inspection guide for this topic. Owing to the current positive experience ASN is open to discussion on the possibility for expansion in the use of internal authorizations. The next activity likely for review for internal authorizations is a restart after refuelling with maintenance. This authorization is currently issued by a local ASN representative based on available technical instructions.

Another special category of authorizations issued by ASN are called generic authorizations. At present these are only used for authorization of releases of radioactive effluents. For these authorizations, an authorization envelope is specified, and if the releases are below the envelope limits, no additional authorization is needed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 **§**3.2 states *"…the regulatory body: (1) shall establish, promote or adopt regulations and guides upon which its regulatory actions are based",* **§**5.4 states *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.",* **§**5.8 states*"…the regulatory body shall define and make available to the operator the principles and criteria on which its judgements and decisions are based."* and **§**5.28 states *"Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."* More guidance can be found in IAEA Safety Guides No. GS-G.1.4 and GS-G.4.1.

S2 **Suggestion:** ASN should formalize the process already established in letters to the licensee into generally applicable regulations or guides describing the format and content of documents to be submitted by the operator in support of applications for authorization, as well as the principles and criteria to be followed. This suggestion applies in particular to the content of Safety Analysis Reports and General Operating Rules, with due consideration of recently issued IAEA Safety Standards and lessons learned from the WENRA harmonization process.

(1) **BASIS**: GS-R-1 **§**5.5 states*: "The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either: (1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator's subsequent activities; or (2) the refusal of such an authorization",* and **§**5.26 states *"The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations."* The IAEA Safety Guide GS-G-1.4 on Documentation for Use in Regulating Nuclear Facilities **§**5.10 states *"The format of a licence will depend upon the content of the authorization and the conditions deemed necessary to the regulatory body for a given stage of the authorization process in accordance with the national legal procedures."*

S3 **Suggestion:** ASN should consider replacing the existing uniform format of approval letters broadly used for many different authorizations by a system of authorizations differentiated according to the subject and importance of the authorization.

(1) **BASIS**: GS-R-1 **§**5.5 states "*The regulatory review and assessment will lead to a series of regulatory decisions. …The regulatory body shall formally record the basis for these decisions"***§**5.10 states "*The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny."* GS-G-1.4 **§**2.27 states *"The regulatory body should establish its own set of internal guidance documents which describe its functions and the methods of performing them. For a regulatory body with responsibilities covering several facilities of the same type, it may be useful to develop written procedures that will make the authorization process consistent among its several technical groups, and among similar facilities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S4 **Suggestion:** ASN internal procedures describing the process of authorization should be further improved or developed in order to optimize participation of various organizational units in the process, to ensure time limits are set up for processing the authorization, and to fix the rules for recording and archiving justifications for decisions made during the authorization. These internal procedures will also contribute to harmonization of approaches among the sub-directorates.

(1) **BASIS:** GS-R-1 §5.2 states *"…Alternatively, activities of a particular type may be authorized in general to be performed in strict accordance with detailed technical regulations…"*IAEA Safety Guide GS-G-1.2 on Review and Assessment of Nuclear Facilities by the Regulatory Body §3.31 states *"In some instances, the operator may propose an alternative approach to that suggested in a guide to achieving a safety objective. In such a case, the operator should be required to demonstrate that its proposed approach will provide an equivalent level of safety."*

S5 **Suggestion:** ASN should continue in collecting experience with internal authorizations and generic authorizations, currently demonstrated as an effective way for enhancing the licensee's prime responsibility for safety, in order to allow for future broadening of their scope without compromising regulatory responsibilities and to take account of the possible impact of competitiveness in the nuclear power industry.

(1) **BASIS:** GS-R-1 §2.4. states *"…This legislation : (1) shall set up objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future; … (3) shall establish authorization and other processes … with account taken of the potential magnitude and nature of the hazard associated with the facility or activity, and shall specify the steps of the processes;",* §3.3. (10) states "*In order to discharge its main responsibilities… …the regulatory body: (10) shall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review."* IAEA Safety Guide GS-G-1.2 on Review and Assessment of Nuclear Facilities by the Regulatory Body §3.34 states *"Whenever submissions for a particular type of facility (or parts thereof) may be repeated many times, it may be appropriate for an operator (or in some cases a contractor, which may be in another state) to provide a submission for a 'reference facility' or a 'generic facility'* and §3.35 states *"…The authorization should be limited to the generic design, the submission of which should be followed by supplementary submissions by the operator of the specific facility."*

S6 **Suggestion:** Based on the positive experience gained with the authorization of the EPR reactor in France, ASN should formalize a pre-certification process for possible future generic (site independent) reactor designs in order to provide for high quality and reasonable time of licensing.

(1) **BASIS:** GS-R-1 §2.4 states *"…This legislation : (1) shall set up objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future; … (3) shall establish authorization and other processes … with account taken of the potential magnitude and nature of the hazard associated with the facility or activity, and shall specify the steps of the processes;…(16) shall define how the public and other bodies are involved in the regulatory process;"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
G6	**Good practice:** ASN has established a sophisticated system of authorizations adequately covering all stages and activities related to the lifetime of a NPP with a graded approach, with due account given to the complexity and safety impact of each activity. This includes involvement of the public in the authorization process.

4.1.2. RESEARCH REACTORS

There are 10 research reactors operating within France with power ratings up to 350 MWth. Research reactors are operated mainly by CEA.

Authorization of research reactors is the responsibility of SD3. There are 15 engineers working in SD3, covering 3 different technical areas: research reactors and facilities, decommissioning and waste management. SD3 has in total 80 different installations under its regulatory responsibility, requiring approximately 150 authorizations per year. A recent authorization activity which was reviewed by the IRRS team was the preparation of the decree for the new Jules Horowitz research reactor.

GS-R-1 §5.3 and 5.4

The authorization process in France for research reactors is generally the same as for other BNI facilities, with some differences due to differences in levels of risk. ASN guidance exists on how to proceed with authorizations for modifications and revisions of SAR and GOR documents and how to classify modifications for research reactors based on the associated safety risk. The scope of SARs for research reactors is described in the "Plan Guide des Rapport de Surete" of November 1995, with the latest revision in February 2001.

The programme for internal authorizations for research reactors is sent to ASN typically 6 months in advance and includes justification for each proposed activity. The justification contains the description of the activity, an inventory of materials, various associated risks, consequences of accidents, and a proposed path for authorization. Two possible authorization approaches are proposed: authorization issued by ASN, or an internal authorization issued by the licensee. Generally, in research reactors internal authorizations are used more extensively than in NPPs due to the generally lower level of risk. ASN evaluates the proposal submitted by the licensee, typically with support from IRSN, and makes its decision. IRRS team members noted several cases where ASN rejected the original authorization proposals by the operator. Rules for internal authorizations were established in a guide issued in 2002. Technical review and examination by ASN is based on relevant basic safety rules and operational feedback from previous experiments. There are 15 basic safety rules used as reference documents applicable to research reactors. The guidance documents relevant for research reactors are formalized in ordinances. For technical assessments by the regulator, IRSN expertise is used extensively. In the case of the Phenix fast reactor, the expertise resides almost exclusively within IRSN.

For the Phenix reactor, there are approximately 5 to 10 authorizations per year, mostly related to experiments and restart after shutdown. In general, the same safety rules apply to Phenix as to other research reactors. There are no specific basic safety rules for fast reactors, although during preparation of the Superphenix 2 project, draft guidelines for future fast reactors were developed. Only one person in SD3 is responsible for the upper level authorizations regarding the Phenix reactor (safety reassessments, decree modifications for example), and the same person is also responsible for ITER and for several other activities. Two other ASN staff members locally handle the lowest level authorisations. ASN has to rely extensively on the technical expertise of IRSN. In IRSN there is one expert working full time for fast reactors and many others involved part time.

Consideration should be given by ASN to investigate whether such limited resources within ASN is adequate to maintain its capability as an intelligent client of IRSN, particularly for future reactor designs

ASN requires that prior to granting of an authorization, the applicant must submit a detailed safety assessment of the proposed installation, which is reviewed and assessed by the regulatory body in accordance with well-defined processes. All such safety assessments are reviewed principally by IRSN, which reports its conclusions and findings to the Standing Committee (Groupe Permanent) which makes recommendations to ASN.

The extent of control applied to research reactors appears commensurate with the magnitude and nature of the hazard presented. For BNIs, safety requirements are typically detailed in the decree. Subsequently, prescription techniques (PT) supplemented with public consultation comments signed by the ministers, the safety report and General Operating Rules submitted by the operator to ASN for its approval, and an Internal Emergency Plan submitted by the operator are required prior to authorization of operations.

ASN subsequently issues guidance to the licensee regarding the safety requirements of the decree.

ASN requires the operator to submit to the Regulatory Body information in support of the application within agreed time scales. For complex facilities (BNIs) authorizations are typically carried out in different stages as required in the decree. These stages are subject to the review and assessment by ASN, IRSN and Standing Committee (GP) for eventual decision by ASN. This process should ensure that feedback from previous stages of authorization is duly considered.

GS-R-1 §5.5, 5.6

The regulatory review and assessment leads to a series of regulatory decisions pursuant to the original decree. Decisions are transmitted to the licensee by ASN in the form of a letter from ASN to the director of the installation. These regulatory decisions are formally recorded and captured.

The regulatory body has clearly defined and established procedures as to when and how these authorization decisions are to be made.

ASN has established performance targets related to the timeliness of regulatory decisions and/or response to a licencee's submission or request. IRSN has not adopted these timeliness goals or targets although IRSN provides a crucial service in ASN's ability to meet their performance targets.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 **§**5.6 states *"any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3."*

S7 **Suggestion:** The timely completion of IRSN reviews was raised as an area requiring improvement. As an example, ASN has performance targets for response to operators of authorization requests. However, there is no means by which ASN can require complementary performance measures of IRSN. ASN may consider further refining these key interlinkages with respect to review and assessment performance management with IRSN.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

G7 **Good Practice:** The internal authorization process permits licensees to undertake activities outside the principal authorization based on guidance principles issued by ASN to the licensee. All proposed authorizations are passed to ASN staff in advance for their review and concurrence.

(1) **BASIS**: GS-R-1 §5.3. states *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented. Thus, for example, a dental X ray machine may require only registration with the regulatory body, whereas for a radioactive waste repository a multistage authorization process may be required".*

(2) **BASIS:** GS-R-1 §5.6 states: *"Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3."*

S8 **Suggestion:** ASN may want to consider formalizing their review and approval programmes for financial guarantees and the associated preliminary decommissioning plans in advance of initial authorization for new BNIs.

4.1.3. FUEL CYCLE FACILITIES

ASN responsibility for fuel cycle facilities (FCF) starts at conversion from UF_4 into UF_6, more precisely when enrichment of uranium with U-235 exceeds 1 percent. Consequently, ASN regulatory oversight includes plants conducting activities at all stages of fuel life: from conversion of UF_4 to UF_6, enrichment to fabrication of fuel, reprocessing of spent fuel, return of low-enriched uranium to conversion plants, and plutonium to the fabrication plant for producing mixed oxide (MOX) fuel. Currently, FCFs in France include:

- Comurhex uranium hexafluoride preparation plant, at Pierrelatte;
- COGEMA TU5 (from reprocessed uranium) and W (from depleted uranium) plant for conversion of uranyl nitrate or UF_6 into U_3O_8, at Pierrelatte;
- Eurodif enrichment plant (from natural uranium) based on gaseous diffusion separation, at Pierrelatte;
- FBFC nuclear fuel fabrication plant (from enriched both natural and reprocessed uranium), at Romans;
- MELOX nuclear fuel fabrication plant for MOX fuel (from depleted uranium and PuO2), at Marcoule;
- COGEMA reprocessing spent fuel element plant, at La Hague; and
- Georges Besse II nrichment plant, at Pierrelatte; commissioning of 2 production units is planned for the period 2007 – 2012.

As can be seen, FCFs are of different ages, with some of them already at the initial phase of decommissioning, while another, namely Georges Besse II, will be commissioned soon. There are two licensees operating FCFs: COGEMA and FBFC. Previously, one of the MOX fuel fabrication plants was operated by CEA, but fabrication stopped in 2003 and decommissioning of the facility will start in 2007.

In SD1 on average 4.5 experts work for FCFs covering a total of 20 BNIs. SD1 delivers 50 to 60 authorizations per year for FCFs. As in the other sub-directorates, it was demonstrated that the use of internal ASN performance indicators was a powerful tool for enhancing timeliness of the authorizations.

GS-R-1 §5.3 and 5.4

The system of authorizations is based on the same regulation for all BNI. Therefore the authorization process for FCFs is to a large extent the same as for other BNIs, and includes a creation decree with associated safety documents (SAR, GOR, EP and recently introduced by the environmental decree of 1999 a waste management plan), authorization of effluents, and authorization of modifications. Before the creation decree ASN requires the submission of a special document called the Safety Option about 5 years prior to submission of the PSAR. The content of this document is specified in a letter, which serves as guidance for the applicant.

As for other BNIs the content of the SAR is specified in an attachment to a letter to the licensees with applicability for all FCFs. All specific issues important for FCFs are adequately addressed in the specification for the content of the SAR: criticality, radioactivity, toxicity and other possible chemical impacts. Feedback from similar installations should be also covered. Due to the limited numbers of some types of FCFs (like centrifugal enrichment), in-country available experience is also limited, and experience from other countries (Germany, Belgium, Sweden, UK, Spain, Russia) is also made use of. Measures taken in order to facilitate future decommissioning should also be addressed in the SAR. A list of specific design basis accidents for each FCF is proposed by the licensee. Usually among the most severe accidents is a seismic event or fire, or a combination of both. From a complexity point of view, the most demanding facilities are reprocessing facilities, mainly because of the toxicity of plutonium.

Full scope PSA studies are not performed for FCFs, mainly due to limited data on reliability of components and in some cases due to the generally lower level of risk. Until now, only limited scope studies have been used to screen out some events. However, risk studies are strongly related to sound implementation of the defense-in-depth approach.

As was the case for other BNIs, PSR is an important tool for identification of the need for safety upgrading. Since June 2006, PSR has been prescribed with a periodicity of 10 years, but it was also used for FCFs upon request by ASN. The PSR includes a comparison for conformity with the original safety case as well as the need for upgrading due to new safety requirements. Examples of more demanding new requirements for FCFs are consideration of chemical risks, consideration of ageing, and evaluation of 10 years of operational experience. Similarly as for NPPs, proposed modifications are categorized into three groups according to their safety significance. Rules for categorization are described in a letter to licensees. Independently of the categorization of modifications, ASN is to be informed well in advance about all activities to allow for timely regulatory action. If the FCF is planned to be in operation for less than 5 more years, compensatory measures may be acceptable to enhance the safety level; for other cases corresponding upgrades may need to be implemented.

Prior to authorization, all submitted documents are examined in 2 steps: a formal review for completeness, and a detailed technical examination. Technical examinations may focus on different safety aspects depending on the type of activity reviewed (criticality, containment of radioactivity, or toxicity). Rule changes can result in modifications to the original creation decree.

A typical authorization for a FCF may be related to a modification such as a change of processes, fuel, or methods. No authorization is needed for restart of a FCF following a break in production unless the break goes beyond the approved GOR. Full authorization of a modification in a FCF typically takes 1.5-2 years.

The reference documents for evaluation of the authorization request are the relevant basic safety rules. IRSN provides the bulk of the technical expertise for the review. The most important limits for operation of a FCF are fixed in a ministerial decree. For example, at the MELOX facility, the total amount of Pu in the facility is limited by ministerial decree. Chemical effects of potential accidents are also reviewed against limits. Combinations of effects are not considered during the review. Both effects are evaluated and the most severe is selected as the basis for the decisions.

IRSN is typically asked for technical support during the review of the authorization, although for some administrative decisions their support is not needed. ASN does not run computer code, and therefore IRSN provides all of the information related to code analyses. The main issue for ASN in such cases is to find a proper balance between the proposals of IRSN and other potential consequences when the authorization is viewed from a broader perspective. For example, from a criticality point of view IRSN may suggest minimizing the amount of fissionable material in a container. Doing so increases the number of transports. ASN must weigh the two issues in making their final decision.

Due to the fact that ASN does not perform independent code calculations, it intends to contract some specific re-calculations abroad (Germany, UK, Belgium). For some very specialized technical areas, the pool of potential experts is limited within a country or even worldwide. True independence may be difficult to establish, and further, this again emphasizes the need for ASN to maintain its 'intelligent customer' capability.

Broader use of internal authorization is also being considered for FCFs. Internal authorizations have not been used at FCFs, but La Hague was recently asked to identify possible activities within the framework of dismantling, when a large number of authorizations may be expected due to the unusual configuration of the plant. The concern for FCFs is the need for independent examination of the internal authorization. This is not a problem for EDF and its NPPs because there are strong central services and hence an easy way to find an independent group of qualified experts from the central organization rather than the specific site. On the other hand, for COGEMA to apply internal authorizations requires using the services of an internal evaluation group from the site itself. ASN will continue its efforts to introduce internal authorizations in FCFs since a large number of authorization applications can lead to large delays in issuing external authorizations.

FCF authorizations involve a number of transportations. Transports from abroad are based on contracts under control of the Ministry of Energy and Raw Materials. ASN reviews and gives its opinion on the contracts.

Operating personnel of FCFs receive operation permits only from the licensee in accordance with the Order on QA of 1984. Capability of personnel is checked only during inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** The IAEA Draft Safety Requirements (DS 316, draft dated 24 August 2006) on Safety of Fuel Cycle Facilities §2.7 *„The design features, controls and arrangements necessary to implement the defence in depth concept shall be identified mainly through a deterministic analysis (which may be complemented with probabilistic studies) of the design and operational regime."* GS-G-1.2 §3.59 states *"As a complement to the deterministic approach, the regulatory body should require an evaluation of the risks arising from the facility. A common method of providing such an evaluation is for the operator to perform a probabilistic safety assessment (PSA)."*

(2) **BASIS:** GS-R-1 §4.1. states *"The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently."* and §3.3. states *" ...the regulatory body: (1) shall establish a process for dealing with applications, such as applications for issuing of an authorization…".*

G8 **Good practice:** ASN internal performance indicators are used as a tool for on-line checking of status of individual regulatory activities with a positive effect on preventing delays in issuing authorizations.

4.1.4. MEDICAL PRACTICES

General requirements for authorizations and notifications

GS-R-1 §5.2

All facilities wishing to use radiation for medical or biomedical purposes must either send a notification (make a declaration) or submit an application for an authorization to ASN. The criteria for the respective mechanisms are specified in the Public Health Code.

Authorizations are required to use: CT scanners for diagnosis; radionuclides in nuclear medicine and biomedical research; blood irradiators; radionuclides in brachytherapy; and installations for external beam radiotherapy. Declarations are required for medical and dental radiological installations. Recently the use of digital angiography changed from requiring an authorization to requiring a declaration, bringing these installations in line with conventional angiography. SD7 (of ASN) advised the IRRS team that elevating all angiography uses to requiring an authorization could be possible. However, it is not expected from the ASN point of view that, even if there is a real potential for radiation injuries to patients to occur in such facilities, a higher level of scrutiny (namely authorization) would significantly improve the effectiveness of the radiation protection (since the same provisions apply). A focus on increasing the frequency of the inspections performed by ASN (see elsewhere in the report) in such practices could be a more powerful tool.

The declaration files and application for authorization files are sent to the local DSNR who acknowledges their receipt (for declarations) and reviews and assesses the authorization files.

Procedures for granting an authorization

GS-R-1 §5.3:

The Public Health Code provides details on what is required to be sent, including a detailed demonstration of the safety appropriate to the facility, activity or practice. The application or declaration, and the accompanying dossier (see below *GS-R-1 5.4*), should provide a detailed demonstration of the safety appropriate to the facility, activity or practice.

The ASN has developed overall guidelines for the examination of individual authorizations and notifications (ASN/AUT/01), giving details of responsibilities, general principles and record keeping.

ASN (in particular, SD7 in conjunction with the DSNRs) are developing detailed internal procedures for reviewing and assessing applications for authorization. Internal guides have been issued for processing application files for authorization to use: CT scanners; external beam radiotherapy; radionuclides in brachytherapy; and blood irradiators. The internal guide for processing applications for the use of sealed and unsealed sources in nuclear medicine is in advanced draft form. An internal guide for registering declarations of medical and dental radiology has also been issued. Finalized guides are used by all DSNRs and ASN.

As well as detailed and structured instructions for review and assessment, the internal guides include a form to keep a record of the process for verification of the dossier and templates are provided for: an authorization, and its covering letter; a provisional authorization (if applicable), and its covering letter; an annulment of an authorization, and its covering letter; and a reminder letter to renew.

All declarations are processed at the relevant DSNR, with summary information sent to SD7. Initially, all authorizations were processed at SD7 but a process of devolution to the regional DSNRs has occurred so that at the time of the IRRS visit only nuclear medicine authorizations were being handled by SD7. SD7 advised the IRRS team that this will also move to the DSNRs by the end of 2006.

It is important to note that the ASN authorization procedures include checking that other regulatory requirements are complied with. These include:

- In the cases of radiotherapy and 'sophisticated' diagnostic equipment, a prior authorization from the ARH (the regional health authority) to allow the provision of such a service (e.g. a CT scanner service) in the area. It should be noted that there have been recent changes to what needs to be authorized by ARH, and that another body (INCa) will assume a new role in authorizing certain medical activities. The regulatory mechanisms for the latter had not been completed at the time of the IRRS visit, and the relationship between the INCa authorization for an activity and the ASN authorization for use needs to be clarified. ASN's position is that they should have no link – each authorization would be granted independently, with the responsibility on the operator to have both authorizations if required.
- Authorization from AFSSAPS with respect to the manufacture and distribution of unsealed sources.
- Compliance with the regulatory requirements set by AFSSAPS for quality control, including the performance of specified tests by an accredited organization.
- Compliance with the technical requirements set by UTE (a standards authority) for medical and dental installations.
- Compliance with the Environment Code in the case of nuclear medicine facilities (and in the future, cyclotrons producing medical radiopharmaceuticals). Initiatives are underway to simplify current environmental requirements with respect to the medical uses of radionuclides. The intention is for the ASN authorization to be sufficient.

The IRRS team was informed that AFSSAPS's role in authorizing the manufacture and distribution of unsealed sources is to be transferred to ASN following the implementation of the TSN 2006 Act (a new decree introducing modifications needed within Public Health Code should be issued at the beginning of 2007). AFSSAPS would retain oversight of the quality control requirements for all medical devices and the responsibility for the pharmaceutical aspects of the

radiopharmaceuticals. As an example, cyclotrons producing radiopharmaceuticals would require an authorization from ASN covering the production and distribution of radiopharmaceuticals. ASN's role (which was not mandated) at a recent incident at a cyclotron, where a person become contaminated and subsequently developed skin erythema, would seem to support the case for authorization responsibilities to be transferred to ASN.

AFSSAPS currently also has a role in the assessment of radiation emitting medical devices. This has effectively evolved into such devices needing to have the CE mark – any device with a CE mark is registered by AFSSAPS, who then will send a list of notified medical devices to ASN (as a result of a formal recent meeting in October 2006). The IRRS team was informed that ASN has concerns that the CE mark may not be sufficient to indicate that a radiation emitting medical device would meet the current IAEA standards and guidance. It should be noted that ASN can ask AFSSAPS to reconsider the use of a medical device if ASN has concerns over the radiation safety of the product (AFSSAPS can withdraw from the market any medical device if the use raises safety issues).

The current UTE standards applicable to medical and dental installations are in need of revision.

While there is no scope for exemption in the use of radiation in medical or biomedical research practices, the use of both declarations and authorizations does provide a system whose processes are broadly aligned with the potential magnitude and nature of the hazards. However ASN might wish to consider whether the documentation and controls needed for the declaration of a dental X-ray practice should be the same as that required for an application for the authorization of a medical X-ray facility.

Guidance for applicants

GS-R-1 §5.4

The Public Health Code provides details on what is required to be sent by the applicant or declarer. There are specific application forms (available from the ASN website) for an authorization to use: CT scanners for diagnosis; radionuclides in nuclear medicine and biomedical research; blood irradiators; radionuclides in brachytherapy; installations for external beam radiotherapy; plus a specific form for the declaration of medical and dental radiological installations. These forms, in addition to having several sections that need to be completed by the applicant/declarer, include detailed information on the additional information and reports that must be included as part of the official dossier.

If the application for an authorization is incomplete, ASN or DSNR must write, by registered mail, to the applicant requesting the missing information. There is a two month period in which to verify that the application file is complete. This time limit is suspended while additional information is being sought.

Some of the information that ASN currently requests may not add any value to the regulation of radiation safety. For example, current applications forms require details of all medical practitioners who will use radiation at the facility. Doctors tend to be very mobile, and any list that ASN has would soon be out of date. It is more effective if criteria are established for any medical practitioners wishing to use radiation under the authorization. In other words, the applicant needs to describe their internal authorization process (that must meet the regulatory requirements for qualifications and experience) and the implementation of this can be audited at any time during an inspection. (ASN having an out-of-date list of medical practitioners adds no value to radiation protection). Other requested information also needs to be scrutinized in terms of whether it adds value to the authorization process.

Regulatory decisions

GS-R-1 §5.5

After the application file is considered complete (see above), ASN or DSNR has a further 6 months in which to notify the applicant of its decision. Further information can still be sought in this second period. If no decision is given in the 6 months, the absence of a response means that the application has been rejected.

All authorizations are issued for 5 years. Provisional licences (for 3 months typically) may be issued in nuclear medicine and brachytherapy for situations where further technical assessments are required after operation has commenced.

The authorization that is issued contains, among other items, technical requirements that must be complied with.

A letter is sent with the authorization explaining the basis for the decision and that the authorization cannot be transferred to another person without an explicit decision by ASN. Further information is given on additional responsibilities.

All declarations are formally acknowledged, together with a reminder of the general conditions that apply.

Procedures for amendment, renewal, suspension or revocation

GS-R-1 §5.6

Submission of an application for renewal is required at least 6 months before expiry. Any change in the conditions of the use of radiation for which the authorization was granted must result in an application for an amended authorization. Similarly, a change in a declared practice must also result in a new a declaration. The forms for both authorizations and declarations provide clear information on what documents need to be submitted, depending on whether it is a renewal or amendment. There do not appear to be any 'automatic' reminders sent to licensees prior to renewal.

The internal guides for processing application or declaration files cover both amendment and renewals.

In common with the note above (under GS-R-1 **§**5.4) the IRRS team was informed that some information being asked for with amendments and renewals might not be necessary for the review and assessment process. Only information necessary for the review and assessment should be requested – compliance with regulatory requirements will be enhanced if the user perceives the relevance of the requested information. Or conversely, requests for information 'for information's sake' can result in resistance to complying with regulatory requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 **§**5.2 states *"For all facilities and activities, a prior authorization, a notification or an exemption shall be in force".*

S9 **Suggestion:** ASN should reconsider the categorization of facilities using X-rays in interventional procedures.

(1) **BASIS**: GS-R-1 **§**5.3 states *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed by the regulatory body in accordance with clearly defined procedures".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

G9 **Good Practice:** While relatively new to authorizing the use of radiation in medical practices, ASN has developed clear requirements for what needs to be submitted, including details to demonstrate safety, and is developing clear procedures for how the information is to be assessed.

S10 **Suggestion:** Notwithstanding the Good Practice G9, it is suggested that ASN completes the development of its internal procedures (nuclear medicine) to cover all medical practices, considering its own experience feedback.

R8 **Recommendation:** Considering the decision to change the role of AFSSAPS in authorizing the manufacture and distribution of sealed and unsealed sources, and X-ray generators (with likely transfer to ASN in 2007), ASN will need to develop technological surveys, in collaboration with IRSN, to assess the safety of new medical devices, using current international standards for radiation safety.

R9 **Recommendation:** The relationship between the ASN authorization for use and the future INCa authorization for a health practice (e.g. cancerology) must be clarified and formalized.

S11 **Suggestion:** The ASN, through its new powers, should issue technical decisions that set radiation safety standards for radiology, nuclear medicine, brachytherapy and external beam radiotherapy installations.

S12 **Suggestion:** ASN might wish to review whether the documentation and controls needed for the declaration of a dental X-ray practice should be the same as for the authorization for a medical practice.

(1) **BASIS:** *GS-R-1* **§***5.4* states *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization."*

G10 **Good Practice:** ASN has developed application and declaration forms that provide clear guidance on the format and content of documents to be submitted by the operator in support of applications for authorization or for notification

S13 **Suggestion:** Notwithstanding Good Practice G10, it is suggested that, for the purpose of simplifying the process for users, ASN reconsiders some of the information it currently requests.

(1) **BASIS:** *GS-R-1* **§***5.5* states *"The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either:*
(1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator's subsequent activities; or
(2) the refusal of such an authorization.
The regulatory body shall formally record the basis for these decisions".

G11 **Good Practice:** ASN has developed procedures for processing applications for authorization that result in either the granting of an authorization or its rejection, including the basis for the decision. Templates for authorizations have been developed for the respective areas of medical uses of radiation.

(1) **BASIS:** GS-R-1 **§**5.6 states *"Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
S14 **Suggestion:** It is suggested that ASN reviews the information it currently requests for amendment or renewal of an authorization or amendment to a declaration.
S15 **Suggestion:** ASN should consider sending a reminder letter to licensees prior to the 6 months before the expiry date of the authorization.

4.1.5. INDUSTRIAL AND RESEARCH PRACTICES

Procedures for granting an authorization

GS-R-1 §5.3:

- Sub-Direction 1 (hereinafter SD1) of ASN issued internal detailed guidance (Guides d'instruction d'une demande d'autorisation), not procedures, on the review and assessment of the information submitted by the applicant. These guides cover practices and activities in industry and research authorized by ASN[1], such as Notes:
- SD1 n° 1-SD-FS 24 version 0 (20/01/2005) for gammagraphy;
- SD1 n° 1-SD-FS 25 version 0 (14/02/2005) for measurement of density and humidity;
- SD1 n° 1-SD-FT-28 version 1 (25/04/2006) for the use of non-sealed sources; and
- SD1 n° 1-SD-FS 26 version 0 (10/08/2005) for detection of lead in paints.

In these guides the extent of the applied control is commensurate with the magnitude and nature of the associated hazard (that is, based on a graded approach) and they are available on the ASN intranet.

The implementation of authorization processes for both diagnostic and therapy uses of radioactive sources in animals (namely horses, cats and dogs) is similar to the uses in industry and research (that is, it covers all users and sources). The use of electrical generators in veterinary applications, mainly in radiography studies, is widely distributed in France and the implementation of such processes is advancing.

Concerning the Code of Conduct on the Safety and Security of Radioactive Sources, ASN issued the table "Etat d'application en France du Code de Conduite sur la Sûreté et la Sécurité des Sources Radioactives" (March 2006), where each item of the Code is referred to the corresponding requirements/guidance established in the legal and regulatory framework (Public Health Code, Labour Code) and/or in the technical prescriptions included in the authorizations. As it is the case for other European directives, the IAEA Code is used by ASN personnel connected with the preparation of regulations but it is not a direct working document for ASN inspectors. Instead of the IAEA Guidance on the Import and Export of Radioactive Sources, ASN complies with Directive 2003/122/EURATOM of the European Union Council concerning the control of high activity sealed sources and orphan sources.

It should be noted that there is a difference in who is licensed for industrial and research uses, depending on whether the facility is a BNI or not. In the case of non-BNIs, the authorization of the use of radiation sources in a practice or activity, is issued by SD1 to an individual (physical person), appointed by its organization, as the primary responsible person for the safe use of such sources. The validity of the individual authorization is five years.

For BNIs (i.e. an industrial irradiator in the context of industrial and research uses), SD1 authorizes the legal person (the organization that will use the sources) instead of a physical person.

[1] about 14 uses for non-sealed sources, 16 for electrical generators and 18 for sealed sources.

The direct responsibility for safety is assigned to the top managerial level of the organization or facility. Dilution of such responsibility is conceivable, but can be prevented if the prime responsibility for safety is assigned to a physical person. The legal person then retains the responsibility for providing the necessary resources to ensure that the delegated person is able to discharge all their responsibilities.

Once an authorization is granted by SD1, the user must complete a form detailing their name and address, the characteristics of the required radiation source, the identification of a source provider certified and authorized in France, etc. IRSN checks this information for monitoring purposes in SIGIS and if it is correct, IRSN approves the request on the same form and sends a copy of the form to the user and keeps the original form. If IRSN does not approve the request because the information detailed in the form is not correct, it sends the form to SD1 for regulatory action.

Practically all the radiation sources (or equipment containing them) used in industry and research are certified and made available in France through identified companies. Therefore if authorized users request such sources or equipment in France, IRSN (by means of its verification process) plays an active part in the systematic control of the authorization system managed by SD1.

Guidance for applicants

GS-R-1 §5.4

SD1 issues forms specifying the information to be submitted by the applicant (*Demandes d'autorisation prévues par les articles R.1333-26 et R.1333-27,* Public Health Code). The forms are available on the ASN website, and include:

- *Fabrication, détention, utilisation ou manipulation de radionucléides ou de dispositifs ou produits en contenant (à l'exclusion des utilisations sur l'homme ou de la recherché biomédicale)*, IND/RN/001;
- *Autorisation d'utilisation des appareils électriques émettant des rayons x ou des accélérateurs de particules (à l'exclusion des utilisations sur l'homme ou de la recherche biomédicale)*, IND/GE/001;
- *Autorisation de détention et utilisation de sources radioactives non scellées et de sources radioactives scellées associées*, IND/RN/004.

The format of the information to be submitted is provided by the application form – answering the questions given in the forms, plus supplying the additional documents (a dossier) specified in the form. Corresponding guidance and applicable regulations are included in the forms. All these documents also include the corresponding regulatory occupational radiation protection requirements, including optimization, controlled and supervised areas, personal protective equipment, work place monitoring, training of radiation workers, local rules, and individual monitoring.

As mentioned above, ASN issued the table *"Etat d'application en France du Code de Conduite sur la Sûreté et la Sécurité des Sources Radioactives"* where each item of the Code of Conduct is referred to the corresponding requirements guidance established in the legal and regulatory framework (Public Health Code, Labour Code) and/or in the technical prescriptions included in the authorizations). Also as mentioned above, ASN complies with Directive 2003/122/EURATOM.

No recommendation or suggestion is made.

Regulatory decisions

GS-R-1 §5.5

The total number of applications and the basis for the granted authorizations are stored in the SD1-IRSN internal database SIGIS[2] at Fontenay-aux-Roses. According to the French regulatory system (Article R.1333-30 and 31 of the Public Health Code), applicants that do not meet all the applicable requisites are informed accordingly and ASN maintain their files *ad infinitum* in stand-by in SIGIS; that is, the authorization is neither granted nor refused. An example is the case of the Thermo Electron Society, supplier of radioactive sources contained in electron capture detectors.

No recommendation or suggestion is made.

Procedures for amendment, renewal, suspension or revocation

GS-R-1 §5.6

The above mentioned forms include options for amendment or renewal of granted authorizations. The applicant must submit to SD1 a new form prior to the end of the validity period (five years) of the current authorization. Each applicant and each authorization has a code, so traceability is easy and rapid by means of SIGIS.

The conditions for suspension or revocation of authorizations are specified in Article L.1333-5, Chapter III, of the new legislative part of the Public Health Code. Before the application of sanctions (suspension or revocation of an authorization) ASN formally notifies the user about the verified violation and, if there is not an immediate radiological danger for persons, establishes a time period of at least one month (Article L.1333-5 of the Public Health Code) for solving the non-compliance of legal requirements; in the case of an emergency affecting the protection of persons, the authorization can be suspended as a precautionary measure. The experience accumulated in SD1 demonstrates that such formal notification is effective for preventing suspension or withdrawal of authorizations.

No recommendation or suggestion is made; the existing forms and the applicable regulations cover this Section.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 **§**5.3 states "*Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented*."

R10 **Recommendation:** ASN should adapt its existing guidance to form formal procedures in the framework of its management system, covering the use of radiation sources in all practices connected with industry and research authorized by SD1.

4.1.6. WASTE FACILITIES

Predisposal Management and Storage of Radioactive Waste

GS-R-1 5.1, 5.3, 6.8, 6.9; WS-R-2 2.1-5.30

Decree 63-1228 of 11 December 1963 requires:

- the applicant to provide a dossier, including a preliminary safety report, for authorization of the creation of a BNI,

[2] Système d'information et de gestion de l'inventaire des sources de rayonnements ionisants.

- the operator to issue a provisional safety report before the commissioning of the installation (for authorization),
- the operator to issue a final safety report after the commissioning of the installation, and
- the operator to provide a safety report concerning future activities, such as when the installation is shut down.

The decree also stipulates that the Ministries of Industry and Environment may require the operator to update the safety report on its installation during its operational phase. Those principles are still applied by the operators and ASN with its technical support reviews at the different stages of the life of the installation.

The guide DSIN-FAR/SD3/No. 50 208/01 of 3 April 2001, on the content of the safety report for non-reactor and non-disposal installations, requires the operator to provide a description of the site (I.2, DSIN-FAR/SD3/No. 50 208/01of 3 April 2001) including the determination of ambient radioactivity in the area. It also requires a dedicated section of the safety report on the management of radioactive effluents (I.6, DSIN-FAR/SD3/No. 50 208/01of 3 April 2001) and the evaluation, measurement, recording and control of these effluents (II.2, DSIN-FAR/SD3/No. 50 208/01of 3 April 2001). It also requires evaluation of potential effects from natural and human induced external events (I.7, DSIN-FAR/SD3/No. 50 208/01of 3 April 2001).

The estimates of expected and potential releases of radioactive material and the radiological exposure of the population in various operational states of the facility must be provided in the study of the impact of the installation that is required by the Environmental Code. The impact in case of an accident must be provided by the study of the hazards posed by the installation, as required by the Decree of 11 December 1963.

The Ministerial Order of 31 December 1999 requires the operator to produce a "waste study" which should describe:

- the objectives to reduce volumes and toxicity of the waste in its installation,
- a description of how wastes are generated,
- characteristics of wastes,
- description of recycling solutions,
- description of pre-treatment and treatment,
- description of the storage of the waste and transport,
- description of the long-term management solutions (e.g. repositories)

The waste study is transmitted to ASN which approves one part of it (the "referential"). ASN reviews the consistency of the arrangements taken or planned by the operators and the different steps of the management of its waste. The review takes into account the requirements for acceptance of the waste packages.

The guide DSIN-FAR/SD3/No. 50 208/01 of 3 April 2001 on the content of the safety report for non-reactor and non-disposal installations requires the operator to provide a demonstration of the acceptability of safety provisions in Part II of its safety report.

The referential part of the study on the management of radioactive waste must be approved by the DGSNR (Ministerial Order of 31 December 1999). Each year, the licensee is required to submit a report on the management of radioactive waste, in compliance with the guide SD3-D-02 of 23 September 2002.

The safety analyses provided by the licensee are assessed by IRSN and, if needed, by one of the four Advisory Committees. ASN grants the authorization to the facility assuming the assessment is satisfactory. The safety case (safety analysis report, general operating rules, internal emergency

plan, study on the management of waste) must be periodically up-dated to take into account changes in the facility. According to the new Law on Transparency and Safety in the Nuclear Field a periodic safety review is also to be conducted every ten years.

Discharge Control*GS-R-1 §5.1; SS115 III.3, III.4, III.13; WS-R-2 5.8*

Discharge control for nuclear, industrial and medical facilities is carried out in principle according to the legislation on public health. ASN is authorized to implement the provisions of the legislation in the nuclear and medical field, whereas some industrial applications and uses of radiation are outside the ASN mandate. Such facilities are referred to as ICPE facilities (installations classified for the protection of the environment)

An ICPE is an installation that is regulated according to a law of 1976 on the protection of the natural environment. Regulations on BNIs and ICPEs are established under different legislation which allows differences in application of safety principles. An installation is classified as an ICPE if it contains radioactive materials beyond specified limits established in a decree which establishes all the criteria justifying the need for the installation to be classified as an ICPE. This classification addresses many more issues than radioactivity. Examples are: uranium mining and milling residues, naturally occurring radioactive material (NORM) treatment facilities, the very low level waste disposal of ANDRA in Morvilliers, uranium conversion facilities, and also various kinds of research establishments.

Many industrial installations in France are regulated as ICPEs. They are licensed by the Prefect after an investigation by local offices of the Ministry for Industry and the Environment.

Legal provisions for the conduct of an environmental impact assessment (EIA) are in place, involving a public consultation procedure.

The first licenses were issued based on the health standards applicable at the time without taking into account any real feedback of experiences from actual releases. This led to a situation where the limits were so much higher than the actual releases that there was no incentive for the operators to reduce the amount discharged. As a result, ASN decided to review all the licences, including those of ICPEs. This review has been in progress since 1999.

The authorizations for discharges at nuclear installations are comprehensive and include discharges of non-radioactive substances such as metals and nitrogenous substances. The authorizations for non-radioactive discharges are consistent with those utilized in the non-nuclear industry.

The authorization procedure for discharges and water intake in the case of a BNI is initiated by the operator who submits the application to ASN. ASN, after ministerial consultation, asks the Prefect to instigate local public consultation procedures. After completion of technical review and public consultations, ASN may be in a position to issue an authorization which includes an authorization to discharge radioactive substances to the environment. For a new installation, a ministerial Decree is needed.

For installations other than BNIs and in accordance with the Public Health Code, discharges are authorized only for very short lived radionuclides. These effluents have to be managed by radioactive decay, with release limits of 7 Bq/l for laboratories and 100 Bq/l for storage tanks of patients treated by I-131. A technical Circular issued in 2001 recommends a maximum value of 100 Bq/l of I-131 and 1000 Bq/l of Tc-99m at the exit of the sewer of the installation (generally a hospital). An assessment of such discharges, carried out by OPRI (now IRSN) in 2001 to verify doses to sewer workers, resulted in a dose estimate of 4 microsievert per year.

In the case of NORM the results from exposure assessment and planned radiation protection measures have to be sent to ASN and IRSN (Order of 2005 May 25). In the case of radon, if the

radon concentration exceeds 400 Bq/m3, the intervention report is transmitted to the Prefect (and sanitary services). After remediation action, new measurements are needed (Act of 2004 July). The Prefect is in charge of the management of polluted sites. In the case of contaminated areas, after an evaluation of the contamination, the Prefect can ask the owner of the site to implement a remediation plan.

The 2006 Law on Transparency and Safety in the Nuclear Field enforces these principles and the decree (which is being prepared in application of the law and will supersede the 1963 decree) will specify the detailed requirements, mainly reflecting the current practices. The 2006 law requires the licensee to periodically review the safety of its installation, at least every 10 years (article 29-III).

Decommissioning

GS-R-1 §5.3, 5.4, 5.5, 5.6; WS-R-2 2.1-4.2, 6.1-6.13

Decommissioning is considered from the creation of the facility (see the 2006 Law on Transparency and Safety in the Nuclear Field, art 29.I, and the draft decree in application of the law). Nevertheless, decommissioning is not a part of the authorization for creation of a BNI. When the operator decides to shutdown a facility, ASN must be notified of the decision and the required documents, including a safety report and general supervision and maintenance rules, must be provided in order to obtain an authorization specifically for the dismantling operations (see the 2006 law about transparency and security in the nuclear field, art. 29. V and the draft decree in application of the law, and previously the Decree of 11 December 1963, modified). As long as the facility is a BNI, the operator must comply with the corresponding requirements. This is verified through inspections. The operator always remains responsible for the safety of its installation, even during decommissioning (see the 2006 law about transparency and security in the nuclear field, art. 28, and previously the decree of 11 December 1963).

To obtain the final shutdown and decommissioning authorization of an installation, the operator must submit different documents. One of these documents is the justification of the chosen end state. The operator must assess the impact of the remaining radioactive materials. Elimination of all nuclear waste areas must be the final objective for the end state and the one that the operator must seek to achieve (see notes SD3-DEM-01 and 02).

The following requirements must be met as part of the decommissioning process:

- providing the decommissioning plan as soon as possible after the decision to shutdown the facility (see the decree of 11 December, the 1963, art 3 & 6 + Note SD3-DEM-01 of February 2003, and the draft decree concerning BNIs being prepared by the ASN in application of the 2006 law on transparency and security in the nuclear field)
- the ability of the operator to provide funds and the technical capability to dismantle the facility and restore a suitable end-state (see the 2006 law about transparency and security in the nuclear field, art. 29, and the draft decree in application of this law)
- waste zoning: every zone of the facility must be classified as a “nuclear waste zone” or a “conventional waste zone”. Moreover, the waste zoning document must be consistent with waste management procedures (see note SD3-D-01 of September 2002)
- a safety report and the general supervisory and maintenance rules (see the decree of 11 December 1963, modified and note SD3-DEM-01). These documents must demonstrate the safety of the dismantling operations, and take into account radiation protection of workers and the impact on the environment.
- a quality management programme including reports to ASN (see Ministerial Order of 10 August 1984).

Public inquiries are organized as necessary when a facility is to be dismantled so that all interested parties have an opportunity to review the decommissioning plan.

The choice between immediate dismantling and deferred dismantling must be justified by the operator on safety aspects. The entombment strategy is not performed in France.

ASN prefers that nuclear installations be immediately dismantled following decommissioning. For example, ASN asked EDF to assess the possibility of carrying out an immediate dismantling of the EL4 reactor (see the decree of 31 October 1996). As a result, EDF changed its strategy and immediate dismantling for the 9 shutdown reactors has been decided.

The operator asking for an authorization of shutdown/decommissioning of a nuclear installation must provide a waste study applying to this phase. The operator has to define the technical solutions for the safe management of the waste resulting from the dismantling work.

Whereas a large volume of radioactive waste of NPPs and nuclear research centres currently undergoing decommissioning may be disposed of at the low and intermediate level waste repository and in the Centre de l'Aube repository, the graphite waste generated by the gas cooled reactors needs another final disposal solution. The 2006 Programme Act on the sustainable management of radioactive materials and wastes set an objective that a repository should be placed in operation by 2013. One part of activated waste coming from the decommissioning of NPPs will be interimly stored in the ICEDA facility on the Bugey site waiting for disposal in the Centre de l'Aube repository after decay, or in the geological repository that should be in operation in 2025. EDF submitted the application for the ICEDA facility in 2005.

For recent facilities, decommissioning is taken into account during the design stage (2006 law about transparency and security in the nuclear field, art 9.14, and the draft decree in application of the law, and previously decree of 11 December 1963), but the decommissioning plan is actually prepared only a few years before the operator declares that the facility will be shutdown.

ASN recommends that the operator put in place a system of internal authorizations to allow the safety system to evolve. These authorizations should not call into question the demonstration of safety and the practical working procedures of the process should be clearly explained and approved by ASN. Most of the BNIs which have an authorization for final shutdown and decommissioning allow internal authorizations. The process for internal authorizations is ruled by two guides, the safety report and the general supervisory and maintenance rules (ref: SD3-CEA-01, SD3-EDF-01), which require review and updating at least every five years.

To obtain the authorization to create a nuclear facility, the operator must provide an environmental impact assessment (Environmental Code, art. R. 122-1, and R. 122-8). This environmental impact assessment describes the site prior to construction. The information could be used to determine background conditions during the end state survey; but in the past, the survey was usually not performed. So, in all current decommissioning decrees for nuclear facilities, it is stated that:

- in the six months following the end of decommissioning activities, the operator must send a report including the data showing that the required final state has been reached based on a new environmental impact assessment;
- the operator must send a document confirming the future use of the facility (or site) and justifying, on the basis of the radiological state of the facility after decommissioning, the monitoring and management measures that are to be implemented (or none if the operator has proved that the end state of unconditional release is reached).

A report must be presented to ASN following the complete cleanup of the site (see SD3-DEM-02). This report is required in order to change the administrative status of the BNI. ASN conducts an

inspection to assess the final state of the facility, and to verify that no waste remains at the facility. Once all requirements are satisfied, a public easement is written and linked to the site.

Disposal

GS-R-1 §5.3, 5.4, 5.5, 5.7, 5.9; WS-R-1 2.1-2.12

A preliminary safety report is required for the authorization of the design and construction of a disposal facility and a more detailed safety case is required for the commissioning of the installation. The "final" safety case of the Centre de l'Aube facility was reviewed and assessed in 1997/1998. The safety case is updated every 10 years. A new safety case is required for the cessation of operation and the monitoring of the post-closure phase. The operator is required to prepare and send annual reports to ASN (specific requirements imposed on the operator, § II.2.5.1). With regard to a geological formation repository, the ASN and its technical support organization reviewed and assessed the "Dossier 2005" produced by ANDRA and gave advice to the Government during the preparation phase of the 2006 Programme Act. This process appears to provide for a thorough and comprehensive review and should be considered for authorization of the design, construction and commissioning of any future geological disposal facility.

After the process leading to the authorization decree, which authorizes the design and construction of a facility, the process for commissioning a disposal facility consists of review and assessment of the "provisional" safety case of the facility including general operating rules, a waste study, and an on-site emergency plan. The review process may lead to further evaluation (e.g. clarifications, additional measures to be taken by the future operator). Some of these additional measures may need to be implemented by the future operator before commissioning the facility. ASN also takes into account the results of tests done by the future operator. The authorization of commissioning the facility is accompanied with specific requirements imposed on the operator. These specific requirements specify that the disposal facilities must be operated in accordance with the conditions of the licence and the relevant regulatory requirements to maintain safety during the operational period, and in such a manner as to preserve the post-closure safety functions assumed in the safety case.

Plans for closure, including the transition from active management of the facility, must be well defined and practicable, so that closure can be carried out safely at an appropriate time. The operator must comply with such requirements and, in the safety case submitted to ASN for cessation of operation and closure, shall indicate how safety is assured in the long term. After reviewing, ASN issues specific requirements attached to the decree authorizing closure and the required monitoring during the post-closure phase of the repository.

The surveillance programme of the Centre de la Manche repository (document produced by ANDRA) applies to the active surveillance period of the repository. It has been reviewed and, after clarifications, modifications and additions, has been approved by ASN. The surveillance programme will be updated in 2009, and, afterwards, every 10 years. The specific requirements imposed on ANDRA, concerning the Centre de la Manche repository (in addition to the decree authorizing entry to the surveillance period) include requirements regarding the long-term record keeping (§ VI). The local authorities will review the report that operators will transmit every 3 years, and require corrective measures if necessary.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §5.6 states *"any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and 12 renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3."*

G12 **Good Practice:** ASN suggests submitting technical modifications of minor safety significance in nuclear facilities undergoing decommissioning to an internal authorization process of the operator under the close scrutiny of the regulatory body. This is considered good practice beyond the requirements of IAEA safety standards on decommissioning, because decommissioning is a chain of modifications and the assessment of modifications along the standards of the regulatory body strengthens the safety conscience of the operator.

4.2 REVIEW AND ASSESSMENT

This section considers review and assessment for each of nuclear power plants, research reactors, fuel cycle facilities, medical practices, industrial and research practices and waste facilities, using the requirements of GS-R-1, listed here, as the basis. The text references GS-R-1 as applicable.

GS-R-1 §5.7 – 5.11

4.2.1 REVIEW AND ASSESSMENT OF NUCLEAR POWER PLANTS (NPPS)

The main activities of review and assessment with respect to NPPs are performed by the SD2 located in Fontenay-aux-Roses. These are mainly the review and assessment of design, modifications, general operating rules, fuel management, periodic safety review, ageing management, and operating experience feedback.

The review and assessment of NPP design/construction and manufacturing of nuclear equipment under pressure are carried out by SD5 located in Dijon.

Organization and Responsibilities for Review and Assessment for NPPs
GS-R-1 §5.1

SD2 has both a line organization with sections and a matrix organization for specific themes. The sub-directorate is led by a director with a deputy for each of four sections. The four sections are Core Behaviour; Materials-Exploitation; Radiation Protection of Environment and External Hazards; and New Reactors, Regulations and Evaluation. The total number of staff (excluding management) is about 25.

ASN has recently reinforced the review of "Organisational and Human Factors," because it is recognized as an important area. Currently there is no legal requirement for a licensee to formally notify ASN of a safety relevant re-organization. Major re-organizations are not common. However, the electricity market will be completely liberated in 2007 and cost reductions with respect to personnel can be expected as in other countries. Because of the planned incorporation of WENRA safety reference levels into the French regulatory structure, there will be a requirement for the utility to notify ASN of a re-organization that may have safety significance. Therefore ASN

should evaluate its needs with respect to staffing and capability regarding the new task of review of organizational and human factors aspects. Refer to Recommendation XX in Chapter 6, Management Systems.

Based on the implementation of Order 9900528 of 1999 and Order 0506414 of 2005 with respect to equipment under pressure, ASN has a new task to review other organizations for acceptance as a Notified Body in conformance with the European Union directive 97/23/CE regarding equipment under pressure. This review of other organizations is carried out by ASN for the N2 and N3 class of equipment. ASN, specifically SD5, considers itself a notified body for class N1 equipments although there is no evidence of the basis for this determination.

Establishment and use of review and assessment criteria for NPP
GS-R-1* §*5.4

ASN has established a set of non-mandatory basic safety rules that describe acceptable methods and criteria for meeting regulatory requirements. These basic rules also refer to French industrial standards. Further guidance on the processes to be carried out by the licensee and the contents of the documents to be submitted are, in most cases, identified in letters from ASN to the licensee, often on a case by case basis. In the nuclear equipment under pressure area, Order 0506414 provides general rules that provide the necessary criteria that must be complied with.

Management of Review and Assessment for NPPs
GS-R-1* §*5.9

SD2 provides the management of review and assessment for NPPs. For the most part, submissions to ASN are forwarded to the TSO (IRSN) with a request for review. In a number of cases, which are defined in advance by ASN management, the resulting review document from IRSN will be discussed for advice in the standing review group for reactors, Groupe permanente de reacteurs (GPR). The licensee, IRSN, and SD2 conduct a review and assessment planning meeting four times per year. Two times a year SD2, IRSN and the licensee conduct a planning meeting to discuss the entire list of dossiers that have to be assessed by GPR. Also every year ASN sends a three year programme to the chairman of GPR describing what issues are expected to be discussed over the next three years.

In SD5 most of the submitted dossiers are reviewed internally because of their higher internal technical assessment capability, and only a few are reviewed by IRSN or a consultant. SD5 tends to maintain its capability for technical review and assessment, but they also try to improve the experience of IRSN by sending them the assessment reports for comment. SD5 also uses a standing committee for advice. This is the subcommittee for nuclear pressure equipment. Although ASN has the right to deviate from the advice of standing committees, SD5 chooses not to do this, which is a different philosophy than SD2. Although not seen as a problem, ASN should ensure that deviating from the advice of standing committees is adequately justified.

Both SD2 and SD5 expect an increase of review and assessment activities in the near future because of new reactor projects.

Performance of major review and assessment tasks for NPP

The team focused on 5 main subjects to gather some insight into the way ASN subdirectorates review and assess these areas and how the sub-directorates relate to each other.

Periodic safety review (SD2*)*
GS-R-1 §5.7, 5.8, 5.10

Periodic safety review (PSR) is conducted every ten years. The PSR is conducted by reactor series (e.g. 900 MW or 1300 MW) as opposed to being facility specific. The main goals are a conformity

check and assessment against current regulations, standards and practices. In 2003 IRSN produced an analysis of the compliance of the PSR with IAEA safety guide NS-G-2.10 (Periodic Safety Review), and concluded that it complied with the intention of this publication. A limited number of additional topics of a more general nature are addressed within the framework of the GPR including human factors (e.g. management of safety, organization) and operating experience feedback. The frequency of review of these aspects is not the same as the PSR, but will be coordinated with the decision making for improvements. One disadvantage of the PSR programme is its extended implementation phase compared with the intention of IAEA and with international practices. IRSN has advised ASN to reevaluate and improve this, in spite of the following positive aspects:

- there is the advantage of evaluation in depth where the PSR is carried out for one series of reactors;
- the PSR programme is more ambitious (may require larger improvements in safety) to compensate for the extended implementation time; and
- there have been several cases where modifications have been carried out for all plants in a short time.

The reevaluation should take into account the safety impact of modifications in the implementation plan. With regard to the safety impact of modifications, IRSN recommended that ASN define acceptable methods of ranking modifications and compare this methodology with international practices. To date, no action has been taken by ASN.

There is no ASN PSR guideline. For every specific PSR project, ASN documents the required scope of PSR in a letter to the licensee. There is also no ASN internal guideline for the review and assessment of the PSR report.

The programme of PSR, as well as the definition of current regulations and practices with which to compare the PSR, is decided in a series of meetings with the GPR. The licensee's PSR submittal, along with the reviews of ASN/IRSN, are sent to GPR for a final recommendation to ASN. The deadline for the ASN decision on the modification programme is determined by the date of the first facility of the reactor series that has to carry out its 10-year outage. During this outage the modifications would have to be implemented. The management of PSR in this way is considered a strong process by which to control the facility configuration and improve safety.

Technical specifications (SD2)
GS-R-1 §5.7, 5.11

Technical specifications (TS) are part of the General Operating Rules. Changes to TS are treated and processed as modifications and are subject to ASN approval. Once the licensee submits the appropriate documents to ASN, IRSN is then requested to conduct the technical review for adequacy and safety impact.

Exemptions from TS requirements are also subject to ASN approval. For this process, the NPP has to justify the exemption and identify the possible safety impact and describe what compensatory measures will be taken. IRSN then conducts a detailed analysis which is very well documented. In some cases the licensee uses PSA to determine the impact on the core damage frequency. ASN accepts this as a way to evaluate the impact. This process is also used in cases where the licensee is seeking a quick decision from ASN.

Ageing management (SD2 and SD5)
GS-R-1 §5.7, 5.9

Ageing management is required by a generic letter of 2001 as part of PSR in relation to the 3rd ten year outage. For each plant the safe operation for ten more years has to be demonstrated based on

the identification of key components, the development of replaceability studies, the definition of a research and development programme and the definition of an inspection programme. In 2006 the GPR discussed the adequacy of the research programmes related to ageing.

One year before the first 30 year outage (scheduled for 2008) the justification file will be discussed in the GPR. After the outage (2009) ASN may approve the continuation of operation based on the results of the inspection program, conformity checks and the implementation of modifications. An ageing management programme must be in place for the period after 30 years. For the 4th ten year outage (plant age of 40 years) ASN will require justification files with a view of the next 20 years, with detailed calculations required for the first ten years of the next 20 years. This approach is mainly based on IAEA documents and guidance. Both SD2 and SD5 have review and assessment responsibilities in this programme. The licensee provides the justification document for the ageing management programme. SD2 and SD5 have divided the dossiers according to their tasks. SD5 will review the pressure vessel, primary coolant pipes, primary coolant pumps, steam generators and the pressurizer. SD2 will review the other relevant dossiers. SD5 also uses maintenance 'doctrines' (policies) for their assessments. It was not clear if SD2 and SD5 use the same approach for review and assessment of the justification files. Within the framework of ageing management is the continuous monitoring and tracking of thermal transients and comparing these with the allowed number for the design lifetime of the plant. SD5 receives a report from each power plant every 6 months regarding thermal transients and verifies this during inspections. From these reports SD5 compiles an integrated file where plants of the same series can be compared. This makes it possible to monitor and compare operating performance and behavior of the different plants. SD5 conducts a detailed review and analysis of the thermal transient status of all plants by comparison of the plants and extrapolation of the results until the end of the design life. If the allowed number of transients is expected to be exceeded there is a structured approach in place to review and assess the condition. First will be a detailed analysis of the cause (decomposition of the problem). This may relax the situation. The next step would be to optimize or limit operation, and finally, there might be a rationale or justification to allow a higher number of transients.

Design and manufacturing of European Pressurized Reactor major components
GS-R-1 §5.7, 5.8, 5.10

EPR components in many cases differ significantly from the N4-type components previously manufactured. The new Order of 2005 regarding nuclear equipment under pressure must be applied. ASN has considered it necessary to review and assess the application of the design requirements of these components during construction and the ability of the manufacturer to make such components. The main differences under the new order are the requirements regarding radiation protection. This includes appropriate materials choice, minimizing of corrosion products and good accessibility for in-service inspection. Another important aspect is the ASN requirement (by letter to the licensee) that the safety of the components of EPR shall be equal to or better than before (safety improvement requirement).

One example of a reactor vessel nozzle and a steam generator were shown. Based on the safety improvement requirement it was possible to require a thorough comparison of several relevant material and manufacturing parameters in order to assess the improvement. In several cases, this has led to changes in construction of the components. Furthermore, it was sometimes necessary to record several more manufacturing parameters than anticipated by the licensee in order to make it possible to demonstrate that all parts are produced the same way.

The conclusion was that ASN has created a very good process to verify the entire manufacturing process from design to operation.

Fuel and core design (SD2)
GS-R-1 §5.10, 5.11

The team looked at the practice for the authorization of new fuel and modified core management schemes. ASN has recently provided the licensee guidance regarding the contents of the dossier to be submitted. ASN is considering formalizing this in the near future. The guidance directs that new fuel will be introduced after completing a test programme in a research reactor, testing fuel pins in operating reactors and then testing of several complete assemblies. After the demonstration of safety and good operating experience the introduction of full batches of the new fuel is allowed. The team concluded that ASN should develop internal guidance for the review and assessment of submissions of new fuel and modified core management schemes.

Use of external technical support for NPPs
GS-R-1 §5.9

The role of IRSN has been previously discussed in section 4.2.1. ASN occasionally needs advice or expertise from experts other than IRSN. Apart from the standing committees, consultants may be asked for their opinion. ASN does not identify and/or maintain a readily available list of consultants that one would consider to have the necessary experience and capability and are sufficiently independent from the licensee.

Operating experience feedback regarding NPPs
GS-R-1 §5.9

According to formal requirements the operators are required to report certain events within 48 hours and follow up with a written report within 2 months. Every three months ASN and IRSN have a meeting with licensee headquarters personnel to discuss all reported national and international events to decide which ones should be analysed more deeply and when this should be completed. ASN uses only the international events from the International Reporting System of Research Reactors (IRSRR) and from the U.S. Nuclear Regulatory Commission (NRC) website, although it has strong contacts with other TSOs through IRSN. More than 20% of reported events are analysed deeply. Non-reportable events are also included for discussion and possible review. Every BNI has been asked in the past to send an annual report on safety of the installation. Part of this report is a paragraph with the results of an analysis of the events that have occurred at the facility. The quality and the contents seem to vary by report (19 site reports are sent). There is no requirement on the licensee to analyse all events that occurred during the year in an integrated manner and report to ASN. GPR meets every three years to discuss operating experience based on an assessment from IRSN.

Use of probabilistic safety assessment (PSA*)*
GS-R-1 §5.8, 5.9

The safety of the French nuclear reactors relies essentially on a deterministic design based on the concept of defense in depth. As a complement to the deterministic approach, probabilistic safety assessments are used to evaluate the risk arising from the facilities. ASN issued a basic safety rule (RFS) on the development and utilization of probabilistic safety assessments. For each series of reactors (900MW, 1300MW), the plant operator drafts a reference PSA. For operating reactors, a summary of the reference PSA is included in the safety analysis report compiled for each periodic safety review. For future reactors, the result of a reference PSA will be provided in the preliminary safety report. Although PSAs are already used for the periodic safety review, in the design of future reactors, in probabilistic event analysis, and in operating plant technical specification exemptions, ASN is very cautious in applying PSA in the regulatory process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 §4.6 states *"The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities".*

R10 **Recommendation**: ASN shall demonstrate that they have the necessary qualifications and expertise to be accepted as a Notified Body for N1 Class equipment as required by EU directive 97/23/CE and to comply with international standards.

(1) **BASIS**: GS-R-1 §5.8 states, in part, that *"...the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgments and decisions are based."*

(2) **BASIS**: GS-R-1 §5.9 states, in part, that *"...A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body..."*

(3) **BASIS:** GS-R-1 §4.3 states, in part: *"if the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants. whoever may provide such advice or assistance (such as a dedicated support organization, universities or private consultants), arrangements shall be made to ensure that the consultants are effectively independent of the operator*

(4) **BASIS:** GS-G-1.2 §3.2 states in part, that *"The regulatory body should provide internal guidance on the procedures to be followed in the review and assessment process ..."*

(5) **BASIS:** GS-G-1.2 §3.4 states, in part, that *"For regulatory efficiency, the findings of the preliminary review should be prioritized on the basis of their potential implication for the overall safety assessment of the facility..."*

S16 **Suggestion:** In light of improving effectiveness and efficiency in the safety review process, ASN:

- should make more comprehensive use of the graded approach, in particular for general operating rules;
- should ensure that external technical support is available and utilized as necessary to support the variance in the regulatory body activities, including identification of acceptable consultants;
- should establish an internal guideline for review and assessment of PSR.

(1) **BASIS:** GS-R-1 §3.3(10) states, in part, that *"In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body:…(10) shall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review;"*

(2) **BASIS:** NS-G-2.10 §3.3 and 6.15 (planning of improvements), §6.14 (prioritization of safety)

S17 **Suggestion**: ASN should consider establishing guidance that ensures that those

subjects of NS-G-2.10 that will be reviewed outside of PSR are accomplished with the same thoroughness and with at least the same frequency as in other formal review processes. The reason for exclusion from PSR should be well justified. ASN should reevaluate the extended implementation of modifications following a PSR, taking into account an acceptable ranking method for implementing modifications. The results of this then should be incorporated in the guideline.

(1) **BASIS:** GS-R-1 §5.5 states: *"The regulatory review and assessment will lead to a series of regulatory decisions…The regulatory body shall formally record the basis for these decisions."*

G12 **Good Practice:** The process for approving exemptions from the technical specifications and documentation for the decision is thorough and comprehensive and can be considered as a good practice.

(1) **BASIS:** GS-R-1 §4.2 states, in part, *"The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency..."*.

S18 **Suggestion:** ASN should review and compare the ageing management assessment methods used by each SD in order to ensure consistency.

(1) **BASIS*:*** GS-R-1 §5.10: *"The RB shall develop its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of the facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout."*

G13 **Good Practice**: ASN has developed a comprehensive programme for monitoring, tracking and evaluating thermal transients during the life of the plant.

(1) **BASIS:** GS-R-1 §5.9 states: "*A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria.*"

G14 **Good Practice:** The review and assessment process, including documentation, of the design, construction, manufacturing, maintenance and operation for primary and secondary components of NPPs can be considered as a good practice.

(1) **BASIS:** GS-R-1 §4.11 states, in part "*...National authorities with the assistance of the regulatory body...shall establish arrangements for the exchange of safety related information..."*

(3) **BASIS**: GS-G-1.2 §A14 states "*The operator should provide details of:*
(2) The arrangement made for root cause analysis of incidents, the lessons learned and the follow-up measures taken,"
§A15 states "*The operator should provide information and arrangements for:*
(a) Feedback of experience relevant to safety from similar facilities and from other nuclear and non-nuclear facilities."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §3.3 states, in part, "*the regulatory body (7) shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated"*

S19 **Suggestion**: ASN should require licensees to do an integrated assessment of all events and report this to ASN periodically. ASN should increase the sources of evaluated foreign events.

(1) **BASIS:** GS-R-1 §5.10, states: "*The regulatory body shall prepare its own programme for review and assessment of the facilities and activities under scrutiny.*"

(3) **BASIS:** GS-R-1 §A7 states: "*In the operation of a nuclear power plant, the regulatory body may require a periodic safety review. In such cases, the regulatory body shall first review and assess the operator's strategy and the safety factors to be evaluated. The regulatory body shall subsequently review and assess the completed periodic safety review.*"

G15 **Good Practice**: The French PSR approach, using extensive advice from the TSO and the Standing Committees and applying it with the same rigour to all Basic Nuclear Installations, is considered a good practice.

4.2.2 REVIEW AND ASSESSMENT OF RESEARCH REACTORS (RR) AND FUEL CYCLE FACILITIES (FCF)

GS-R-1 §5.9, 5.10, 5.11

The following items were evaluated and compared with the activities for NPPs: PSR (including ageing management), experiments, general operating rules, modifications, PSA application, operating experience feedback and internal authorizations.

The PSR process (including ageing management) for FCFs and RRs is conducted in the same way as for NPPs and is a strong tool for major safety improvement of RR and FCF facilities. At FCF special attention is given to criticality and chemical hazards. There is a strong intention to implement modifications (e.g. earthquake), although they are often delayed. Guidelines concerning method and contents are available in SD3 and are a pilot for other subdirectories.

The review and assessment of modifications, operating guidelines and experiments is managed in a structured manner and comparable to NPPs. In the RR area there is an increased use of internal authorizations and an increased level of local (DSNR) authorizations. The majority are handled locally. In the FCF area there are no internal authorizations, although the process is being considered by ASN.

At RRs and FCFs there is no overall PSA application for the determination of risk for the various facilities due to the individual designs of the facilities. However, there are some dedicated and specific applications that are utilized in both types of facilities areas. There is no requirement for the operator to report an annual assessment of Operating Experience Feedback. In the RR and research laboratories area there is a three year report from CEA about safety management, and some event analysis is addressed in that report.

The incident reporting process is the same as for NPPs, including INES rating and public information. SD1 and SD3 perform a combined statistical analysis of operating events at RRs, research laboratories and FCFs and use it for planning of the annual inspection programme and

preparation of corrective measures. The exchange of information between SD3 and SD2 (RRs in SD3 and NPPs in SD2) regarding regulatory approaches was infrequent and informal and could be improved. There was no formal or routine communication mechanism in place to improve the communications between the two subdirectorates.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **Basis:** GS-R-1 §3.3 states: "*In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body:… (7) shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated;*"

G16 **Good Practice:** The annual statistical analysis and documentation of events for research reactors and fuel cycle facilities provides a valuable input to the regulatory programme.

4.2.3 MEDICAL PRACTICES

GS-R-1 §5.9:
In performing the review and assessment of the application file for an authorization to use radiation in a medical practice, ASN/DSNR considers how the following elements of the IAEA Basic Safety Standards (BSS) are to be implemented and hence is able to satisfy itself that the requirements of GS-R-1 §5.9 are met.

Responsibilities of the licensee: *BSS §II.1 – II.3*

The regulations assign medical practitioners the responsibility for prescribing a medical exposure.

The regulations assign medical practitioners the main responsibility for overall patient safety in the prescription and delivery of the medical exposure. Furthermore, there is a responsibility assigned to the medical physicist to assure that the prescribed dose has effectively been delivered to the patient.

The regulations require that the medical practitioners and paramedical personnel (MER) have appropriate training. This includes a specific requirement for radiation protection training in patient protection. All such personnel are required to have received radiation protection training by an approved person before 2009.

The regulations establish medical physics as a defined profession and set criteria for the training and the trainers, and the means for recognition as a qualified expert in medical physics (PSRPM).

The regulations require medical facilities to have a "medical physics plan", clearly establishing the facility's requirements for medical physics and how this will be met. All radiotherapy and nuclear medicine facilities must have a PSRPM on site and other medical facilities must have access to a PSRPM.

The regulations establish radiation protection officers (PCR), and set criteria for the training, the trainers, and for continuing professional development.

The IRRS team was informed that there is a significant shortage of PSRPMs in France, and strict compliance with the requirements for such personnel is proving difficult to achieve. Training programmes for medical physicists, with both academic and clinical components, has been established but the shortfall will continue for some time.

Justification of medical exposures: *BSS §II.4– II.9*

The regulations (PHC) explicitly establish the principle of justification.

The professional societies in radiology, dentistry, nuclear medicine, and radiation oncology are developing, in conjunction with other bodies including ASN, publications that include guidance on indications for appropriate examinations or procedures. Adherence to these published guides, as they become available, should be the basis for the implementation of justification. ASN may need to explore means for achieving this. Individual justifications are required to be recorded in the prescription and final report of each examination.

Radiation use in biomedical research falls into two categories: uses where the use of the radiation itself is the subject of the research (e.g. trialling new radiopharmaceuticals for a given procedure); and uses of radiation which are simply standard diagnostic (typically) procedures being used to monitor or assess the efficacy of a particular aspect of the research. With this latter category, the research is not about radiation – the radiation is merely a tool in the research programme. The former category quite clearly needs an authorization in its own right, and the ASN authorizations cover this. The latter category concerns patients who are being subject to standard medical radiation examinations, but without necessarily a direct benefit. Hence it is a question of justification – is the exposure of the patients in the research trials justified in terms of benefit to society, etc, versus the potential harm to the patients. This latter (more common) category does not seem to be effectively covered by the French system in an appropriate manner.

Discussions during the IRRS mission would suggest that the regulation in France of the use of radiation in biomedical research needs further development. To this end it is suggested that the role of ASN is to require that all research proposals submitted to the appropriate ethics committee contain a statement that radiation is, or is not, being used. And if radiation is to be used, the research proposal must be accompanied by a written statement from a qualified medical physicist (PSRPM) giving an estimate of the patient dose, based on the procedures to be used and where they will be performed, and the ensuing risk (based on the age and sex of the patients in the trial). The ethics committee then decides whether the exposure is justified or not.

Breast cancer screening using mammography is performed in France for women aged over 50.

The IRRS team was informed that the medico-legal uses of radiation are being reviewed, particularly in the context of occupational medicine.

Optimization of protection for medical exposures: *BSS §II.10 – II.20*

The regulations (PHC) explicitly establish the principle of optimization.

An overall comment is that the main components are in place for ensuring the optimization of radiation protection in medical exposures, but they are fragmented across many decrees, orders, decisions, and circulars, and many of these are in need of being reviewed and up-dated.

A few particular comments follow:

- The manufacture and distribution of sealed and unsealed sources are required to have an authorization from AFSSAPS. In the case of radiopharmaceuticals, these authorizations are linked with a pre-marketing approval. For medical devices, the authorization does not cover safety issues in the case of equipment having the CE mark ; it covers only protection radiation issues in relation to the facility where the devices are manufactured or stored (before supply).
- There are regulatory requirements for internal and external quality control checks, including calibration in radiotherapy, set by AFSSAPS. The actual tests are detailed in AFSSAPS decisions. The persons or organizations that can perform the tests are also specified in AFSSAPS decisions.
- In radiology, equipment and installations must meet the requirements of the relevant UTE standards, as verified by an approved person or organization.

- Controls (both quality control and radiation protection) must be performed at commissioning and periodically thereafter, as specified in the respective regulations by approved persons or organizations.
- Since 2004, dose measuring devices must be fitted to new equipment.

Guidance levels: ***BSS §II.24– II.25***

The role of diagnostic reference levels (DRLs) is established, by ministerial order, in radiology and nuclear medicine. Results of surveys have to be reported annually to IRSN. However compliance has been poor to date. An IRSN initiative is underway to help facilitate this process by providing radiologists assistance, via software, for dose calculation. The shortage of medical physicists also has an impact on being able to comply with this regulatory requirement.

ASN will need to collaborate with IRSN regarding the information collected and its analysis.

Dose constraints: ***BSS §II.26– II.27***

The regulations specify that dose constraints must be established for volunteers providing support and care to patients, but it is noted that the corresponding ministerial order has not been issued as yet.

Maximum activity for patients in therapy on discharge from hospital: ***BSS §II.28***

The regulations require that patients undergoing diagnostic or therapeutic procedures using radionuclides must be given oral and written guidelines on radiation protection that are of use to the patient, his/her relations, the public and the environment. At the time of the IRRS visit, such information was not standardized. Harmonized information is due to be issued by the end of 2006.

Investigation of accidental medical exposures: ***BSS §II.29– II.30***

There are regulatory requirements to immediately report accidental medical exposure to ASN in the case of all events that could have an effect on the health of persons, including patients, and to AFSSAPS in the case of accidents involving medical devices.

France has had the misfortune to have had several serious accidents in radiotherapy in the last two years resulting, in some cases, in death.

The most recent accident illustrated that there needs to be a greater awareness in medical radiation facilities of the need to report any accident to ASN as soon as it becomes evident – there was a delay of about one year in the most recent case. Once notified ASN set in motion appropriate actions to inspect, review and report on the incident, in conjunction with other authorities.

Dissemination of information on means of minimizing the recurrence of such accidents has been undertaken by ASN, alone and jointly with AFSSAPS. Input from the profession has also been sought.

The most recent accident has resulted in the Minister of Health charging ASN and another ministry inspectorate (General inspectorate for social affairs – IGAS) with coming up with national strategies for minimizing the likelihood for future accidents in radiotherapy.

ASN sees it as paramount that all accidents and incidents are reported immediately. ASN recognizes that compliance is higher if the licensees see that ASN's focus is on the prevention of further such accidents, rather than punitive actions.

Records: ***BSS §II.31 – II.32***

There is a regulatory requirement that medical practitioners keep in a report all the information regarding the justification of an examination, the protocols used and the procedures performed, as well as information that would be needed to be able to perform an estimate of the doses received

by the patient. A ministerial order has been issued in 2006 to provide further detail on the information required.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** ***GS-R-1 §5.9*** states that *"A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:*
(1) the available information demonstrates the safety of the facility or proposed activity;
(2) the information contained in the operator's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and
(3) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety".

G17 ***BSS §II.1 – II.3 Responsibilities of the licensee:***
Good Practice: In the context of medical exposures, the French regulatory framework establishes appropriate responsibilities and requires personnel (medical practitioners, medical physicists, radiation protection officers) with appropriate training and qualifications. There are specific requirements for training on patient radiation protection.

R11 **Recommendation:** ASN should consider lobbying government and the appropriate ministries with a view to further resources being made available to increase the number of medical physicists.

G18 **BSS §II.4– II.9 Justification of medical exposures:**
Good Practice: The French regulatory framework clearly establishes the principle of justification in medical exposures and, further, requires records to be kept in the patients notes for such justification. The professional societies are developing guidance on justification.

S20 **Suggestion:** That ASN encourages and assists the professional societies so that publications are available on justification for all uses of radiation in medicine. ASN should explore means for ensuring adherence to the guides.

R12 **Recommendation:** That the ASN sets up a system to ensure appropriate justification of persons exposed to radiation as a result of being in biomedical research trials, where the use of radiation is not the focus of the research.

R13 **Recommendation:** That the ASN ensures that the review of medico-legal uses of radiation takes into account the current international recommendations of the IAEA, WHO

R14 **BSS §II.10 – II.20 Optimization of protection for medical exposures:**
Recommendation: That ASN performs a review of all the orders and circulars and the UTE standards to ensure that the technical requirements for ensuring optimization of medical exposures in external beam radiotherapy, brachytherapy, nuclear medicine, interventional radiology, medical radiology and dental radiology meet current international standards, including the IAEA BSS and other documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S21	**Suggestion:** That ASN considers means for extending to existing X-ray machines (especially those used primarily for children) the commendable regulatory requirement for new X-ray machines to be fitted with dose measuring devices.
G19	***BSS §II.24– II.25 Guidance levels:*** **Good Practice:** The regulatory requirement for reporting small annual patient dose surveys to IRSN as part of implementing DRLs is to be commended.
S22	**Suggestion:** ASN should assist IRSN in exploring all means to help users comply with the requirement for reporting doses. ASN needs to establish with IRSN how the collected information is to be fed back into the regulatory programme.
G20	**BSS §II.28 Maximum activity for patients in therapy on discharge from hospital:** **Good Practice:** The regulations require that patients undergoing diagnostic and therapeutic procedures using radionuclides must be given oral and written guidelines on radiation protection that are of use to the patient, his/her relations, the public and the environment.
S23	**Suggestion:** That ASN works with the appropriate bodies to ensure that harmonized guidance for patients undergoing diagnostic and therapeutic procedures using radionuclides are issued as soon as possible.
S24	**BSS §II.31 – II.32 Records:** **Suggestion:** That ASN should considers carefully, taking into account the type of medical exposure, what information is required to be kept so as to avoid an unnecessary administrative burden on the medical practitioner.
G21	**BSS §II.29– II.30 Investigation of accidental medical exposures:** **Good Practice:** ASN has taken appropriate steps to investigate reported accidental medical exposures, to widely disseminate information on the accidents, to solicit input for further improvement from licensees and professional societies, and to remind licensees of the existing regulatory requirements.
S25	**Suggestion:** ASN investigates all means of making licensees more aware of the need to immediately report any accidental medical exposures, and why such immediate reporting will help radiation protection.

4.2.4 INDUSTRIAL AND RESEARCH PRACTICES

No recommendations or suggestions are made. SD1 regulatory activities are performed in compliance with these Sections of GS-R-1, including regulatory aspects of occupational radiation protection concerning the use of radiation sources in industry and research, which are covered, particularly, by Section 5.9.

Item (3) of Section 5.9 is a good practical example. SD1 recently received a submission of the AREVA Society for authorization concerning a new model of an accelerator of electrons VARIAN LINATRON M9 foreseen for radiography (non-destructive tests) of heavy elements of nuclear power reactors. As it is a new model where there is no previous experience, SD1 requested technical support from IRSN. IRSN's response, dated 6 November 2006, details a number of technical aspects to be clarified by the applicant, including neutron detection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** (1) GS-R-1 **§**5.7 states "*Review and assessment shall be performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity*." (2) GS-R-1 **§**5.8 states "*In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based*." (3) GS-R-1 **§**5.9 states *"A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:*

(1) the available information demonstrates the safety of the facility or proposed activity;

(2) the information contained in the operator's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements, and

(3) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety."

(2) **BASIS:** GS-R-1 **§**5.10 states "*The regulatory body shall prepare its own programme of review and assessment of the facilities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout."*

(3) **BASIS:** GS-R-1 **§**5.11 states "*Any modification to safety related aspects of a facility or activity (or having an indirect but significant influence on safety related aspects) shall be subject to review and assessment, with the potential magnitude and nature of the associated hazard being taken into account*."

G22 **Good Practice:** The regulatory activities performed by SD1 in industry and research are covering all these sections of GS-R-1.

4.2.5 WASTE FACILITIES, DECOMMISSIONING AND REMEDIATION

Predisposal Management & Storage of Radioactive Waste

WS-R-2 2.1-3.16; 7.2-7.5

As a BNI or part of a BNI, a radioactive waste storage facility must be in compliance with the legislative and regulatory requirements, including the periodic safety review of the installation (see the 2006 Law on Transparency and Safety in the Nuclear Field and the draft decree in application of this law). The safety file produced by the operator is reviewed and assessed by the ASN and its technical supports (IRSN and Advisory Committee).

A periodic safety review shall be carried out every ten years of the BNI (see the 2006 Law on Transparency and Safety in the Nuclear Field). Although this requirement was not legally binding in the past, most of the predisposal management facilities have undertaken such reviews. The

content of a periodic safety review has been established in the guide SD3-CEA-05 of 2 December 2005 for installations operated by the CEA. This requirement should be extensive to other facilities as the ICPE. A prefect can ask the operator to provide a study which could looks like a PSR (art. 37 decree of 77-1133 of 21 September 1977). But it is not actually systematically required.

The PSR should be commensurate with the hazards posed by the installation. Asking for a periodic safety review of a storage of radioactive waste in an hospital managed by radioactive decay is not really appropriate, nevertheless it will be more appropriate to request for a periodic review of the internal plan for the management of radioactive waste inside this kind of facilities.

The ASN and its technical support review and assess the overall process of ANDRAS's studies, including aspects concerning the waste (ANDRA's dossier 2005, inspections...).

In addition, the ASN and its technical supports periodically review the overall strategy of each main producer in the field of radioactive waste management. This review includes the objectives of the waste producer with regard to pre-treatment, treatment and conditioning of its wastes.

Discharge Control

WS-R-2 5.8; SS115 III.3, III.4, III.13

The ASN is in the review and assessment area closely collaborating with the IRSN and is to some extent dependent on IRSN for technical support as well as for developing guidelines for both the operator and the ASN related to discharge assessment. The relationships with IRSN appears functional – the ASN can perform independent analysis in which IRSN's analysis is weighed in, and can set up other review committees for specific purposes.

The applicant has to demonstrate that adequate attention has been given to the principles of optimization and best available technique (BAT). The dose limit of 1 mSv (for sum of practices) is applied but optimization is not based on source-specific constraints. Assessment of optimization and application of BAT is made on the basis of review of technical and managerial options – recurrent reviews are performed where the operator may be forced to a renewed study of technical and managerial options and implement these, if feasible.

Realistic dose assessments for forecasting and/or determining doses to the population are based on actual population data as well as food habits etc. Some conservatism is nevertheless built into the procedure. Guidelines for definition of the critical group have been developed by the IRSN.

Resulting critical group doses are, according to assessments, in the order of 9 microSv for the La Hague plant and 7 microSv or less for the EDF power plants. Even under pessimistic assumptions, based on some observations on the specifics of the limits, public protection would be well within guidelines issued by the Agency. Operators publicize critical group doses annually and communicate these regionally. Discharge levels are included in the ASN Annual Report but not the critical group doses. Although the public may access data from the national monitoring network, there is thus no comprehensive documentation available to the public that informs on, assesses and compares discharge and public dose data from all BNIs.

Decommissioning

WS-R-2 6.1-6.13; 7.2-7.5

The ASN can require to review and assess the safety system of reference in case of specific circumstances and at least every 10 years. The process of internal authorizations requests the operator to review and update periodically (at least every 5 years) the safety report and the general supervisory and maintenance rules.

The decommissioning plan and the associated documents are assessed by the technical support organization of the ASN (IRSN). Regularly, technical meetings are organized involving the ASN and the IRSN to follow the process leading to the final dismantling plan of the facility and comments are addressed as necessary to the operator. Moreover, the operator can dismantle only after having obtained the authorization from the ASN.

Disposal

WS-R-1 3.8-3.11

The likely and unlikely events and process to be considered in a safety case are proposed by the operator (ANDRA) of the repository and approved by the ASN. The ASN provided some guidance in this field (RFS I-2 and RFS III.2.f). The safety case is reviewed and assessed by the ASN and its technical support organizations (IRSN, Advisory Committee). It must be noticed that the ASN fully relies on the proven professional expertise of the IRSN.

Assumptions used in the safety assessment for disposal facilities are defined in the safety case produced by the operator and reviewed/assessed by the ASN and its technical supports. In addition the operator has to provide the ASN with several annual reports dealing, among other things, with non-conformities, the quality of the waste packages, etc. (see the specific requirements imposed on the operator of the Centre de l'Aube repository § I.6). The annual report presented by the operator of the disposal facilities use to address the occupational exposure and its assessment during the operational phase.

Periodic safety reviews (every 10 years) are required by the 2006 law about transparency and Safety in the nuclear field, which enforces the past and current practices. These periodic safety reviews should take account of the evolution of the facility; the experience gained in operation and more generally the evolution of knowledge in the field of disposals on a national and international ground. After reviewing of the safety case, the ASN may issue new requirements if necessary.

In the cases of the ICPE, installations that are regulated according to a law of 1976 on the protection of nature and on ICPE, they are not obliged to comply with the ASN safety requirements. This means, between others, that ANDRA disposal facilities of very low radioactive waste are required to perform a periodical safety reassessment of such facilities only if the prefect will request it.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §3.3(6) states: *In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body: …. (6) shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public.*

R15 **Recommendation:** ASN should consider inclusion of doses to the critical group from Basic Nuclear Installations in its Annual Report as well as descriptions of their meaning in terms of public health protection, and should assess the cause for differences between sites and different operational years.

(1) **BASIS:** GS-R-1 §5.11 states *"Any modification to safety related aspects of a facility or activity (or having an indirect but significant influence on safety related aspects) shall be subject to review and assessment, with the potential magnitude and nature of the associated hazard being taken into account."*

(2) **BASIS:** GS-R-1 §A.7 states *"In the operation of a nuclear power plant, the regulatory*

body may require a periodic safety review. In such cases, the regulatory body shall first review and assess the operators' strategy and the safety factors to be evaluated. The regulatory body shall subsequently review and assess the completed periodic safety review."

(3) **BASIS:** WS-R-2 §5.23 states *"The radioactive waste storage facility shall be designed on the basis of the assumed conditions for its normal operation and assumed incidents or accidents. It shall be designed and constructed for the likely period of storage, preferably with passive safety features, with the potential for degradation taken into account. Provisions shall be made for regular monitoring, inspection and maintenance of the waste and the storage facility to ensure continued integrity. The adequacy of the storage capacity should be periodically reviewed, with account taken of the predicted waste arising and the expected life of the storage facility"*

S26 **Suggestion:** For coherence and consistence, the periodic review and assessment (PSR) of the radioactive waste management facilities should be considered and included in the proper regulations for all type of facilities operating in the country; no matter if they are INB, ICPE or activities authorized according to Art. L.1333.4 of Code of Health. The PSR should be commensurate with the hazards posed by the installation and should take due account of the magnitude of the waste study, likely period of storage, the preferable use of passive safety features, the potential for degradation during that period and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate.

(1) **BASIS**. WS-R-5 §5.7 states *"This initial plan shall be reviewed and updated periodically, at least every five years or as prescribed by the regulatory body, or when specific circumstances warrant, such as if changes in an operational process lead to significant changes to the plan. Revisions or amendments shall also be made as necessary in the light of operational experience gained, new or revised safety requirements or technological developments. If an incident or accident occurs, the decommissioning plan shall be reviewed as soon as possible and modified as necessary".*

G23 **Good Practice:** As in France nuclear facilities under decommissioning stay to be BNIs until they are released from regulatory control, they are subject to the requirement of a PSR every ten years. The process of internal authorizations even requests an update of the safety report every 5 years. This is considered good practice exceeding the requirements of IAEA safety standards on decommissioning, because the status of facilities changes considerably under decommission. In view of a time frame of about 20 years for the dismantling a complete assessment of the achieved status every 5 years seems to be adequate.

4.3 INSPECTION AND ENFORCEMENT

This section considers inspection and enforcement for each of BNIs, medical practices, industrial and research practices and waste facilities, using the requirements of GS-R-1, listed here, as the basis. The text references GS-R-1 as applicable.

GS-R-1 §5.12 - 5.24

4.3.1 BASIC NUCLEAR INSTALLATIONS

GS-R-1-1 §5.12, 5.13

ASN has initiated extensive and comprehensive programmes related to inspection and enforcement at basic nuclear installations (BNIs). Basic nuclear installations include nuclear power plants, research reactors, and fuel processing facilities. Inspection programmes are developed and inspections conducted to verify that the operator is in compliance with conditions established in the operating authorizations. The activities of suppliers and contractors are monitored by observations of ongoing activities and the operator is held responsible for the quality of the material, components, and services provided by the contractor. Enforcement actions were somewhat informal for lesser significant non-compliances, although the recently enacted TSN 2006 Act provides for clearer authority for sanctions. The enforcement mechanisms and procedures for implementing this new law have yet to be developed in detail. However, the general enforcement philosophy was understood by the inspection staff interviewed.

The inspection and enforcement programme ensures that facilities, equipment, and work performance meet all necessary requirements; that relevant documents and instructions are being complied with; persons employed by the operator are appropriately trained and qualified; non-compliances with operating authorizations are complied with within a reasonable time frame; lessons learned are identified and propagated to the regulatory body (but not necessarily to other types of facilities); and the operator is managing safety in a proper and responsible manner.

The regulatory authority makes it very clear that the operator has the prime responsibility for safe operation of the facility.

4.3.2. INSPECTION

GS-R-1-1 §5.14

ASN has, in general, implemented a planned and systematic inspection programme for BNIs. Development of the annual inspection programme is based upon input from the technical support organization (IRSN) including review of operating experience, input from the Regional DSNR offices, input from the Sub-Directorate related to the type of facility to be inspected, and the core inspection activities as determined by ASN. The inspection programme is comprised of three major components: 1) the core inspection activities which are conducted at all BNIs; 2) national inspection priorities; and 3) site specific additional areas of emphasis as determined by the local DSRN head. The amount of inspection (number of inspections) conducted is determined by the potential hazards associated with the type of facility as well as the operating and regulatory history of the facility. Nuclear power plants and fuel cycle facilities would typically receive more inspection than would research reactors. ASN maintains an awareness of operator inspection and audit activities at BNIs. Although a number of sources of information were utilized in the development of BNI inspection programmes, it did not appear that results of the Periodic Safety Reviews or operating experience reviews were extensively used in the programme development. ASN does not currently have a developed and documented inspection oversight programme for the human factors, human and organizational performance, and safety culture areas of criteria their mandate. Although compliance inspections have and continue to be carried out in these areas,

including during reactive inspections following some reported events, few clear regulatory requirements exist in these areas. At present, ASN noted that they are principally in a "fact finding" mode in carrying out "inspections" in these areas. In developing their annual inspection programme, ASN does not have a documented and systematic means of risk-informed decision-making in determining the priorities for the coming year. While core elements, national and local priorities are considered in the formulation of this program, a more structured risk assessment process might improve the overall basis for the programme. A schedule for the periodic assessment of the inspections programme does not exist.

GS-R-1-1 §5.15

ASN conducts both announced and unannounced inspections on a continuing basis. A resident inspector programme is not utilized, although the regional DRSN offices designate lead inspectors for each facility. For announced inspections, the operator is typically notified of the general inspection subject matter or topic approximately one month in advance. Other inspections (about 20%) are conducted with no prior notification to the operator. Inspections are occasionally conducted during night shifts and on weekends. Guidance to this effect is contained in inspection guidance documents. Most inspections are typically conducted by two ASN inspectors and one IRSN expert over a one day period. Longer duration inspections are conducted during refuelling outages, maintenance outages, in-depth inspections, and the ten-year PSR/modification outage. ASN does not utilize contractors to conduct inspections.

GS-R-1-1 §5.16

In addition to scheduled inspections, ASN also conducts reactive inspections in accordance with established guidance when they determine that facility conditions warrant immediate investigation. ASN makes use of a low threshold reporting system to assist in its understanding of facility conditions. Guidance used in determining whether an event is significant enough to warrant immediate investigation has been developed.

GS-R-1-1 §5.17

Inspection findings are communicated during an exit meeting and in writing to the operator before the inspectors leave the site following an inspection. This preliminary information is followed by a formal inspection letter to the operator, typically within 3 weeks following the inspection. This inspection letter provides a categorization of issues regarding non-compliances and other issues requiring corrective actions (Category A), requests for additional information (Category B), and observations (Category C). Internal inspection reports are also generated to document additional details and information regarding the inspection. This information is subsequently used for preparing specific inspection plans and as a knowledge management tool.

ASN staff develops a profile for each site each year comprised of operating information, inspection history details, and the collective judgement of DSNR. This profile is used to identify potential issues that may be present at other facilities and also as a knowledge management tool for future inspections and ASN staff use. Profiles are also used in preparation for annual discussions with the operator.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 *§*5.14 states, in part, regarding establishment of an inspection programme: *"The regulatory body shall establish a planned and systematic inspection programme."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2) **BASIS:** GS-G-1.3 *§*4.5 states, in part, regarding establishment of an inspection programme: *"The regulatory body should consider the following: …- the safety analysis performed by the operator and the results of regulatory review and assessment; …- operational experience and lessons learned from operating the facility and other similar facilities as well as the results of research and development; …- inspection programmes of the regulatory bodies in other States."*

S27 **Suggestion:** ASN should formalize the way of considering use of the results of periodic safety review, as well as operational experience in the development of BNI inspection programmes.

S28 **Suggestion:** ASN should consider a formal periodic assessment of the inspection programme to evaluate its continued effectiveness, including consideration of risk informed insights.

S29 **Suggestion:** ASN should further develop guidance for providing inspection oversight of human factors, human and organizational performance, and safety culture areas of their mandate.

G24 **Good Practice:** ASN inspectors develop detailed agendas based upon off-site preparation activities that are used to facilitate on site inspection conduct.

(1) **BASIS:** GS-R-1 *§*5.17 states: *"Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process."*

G25 **Good Practice:** ASN inspectors document inspection findings in at least 3 documents related to an inspection. Documentation of inspection results is readily retrievable for use in inspection programme development as well as serving as a readily available resource for recalling the regulatory history of a facility.

(1) **BASIS***:* GS-R-1 **§**4.7 states "*In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes".*

G26 **Good Practice:** ASN has a robust and comprehensive accreditation programme for its inspectors.

4.3.3 *ENFORCEMENT*

GS-R-1 §5.18

Enforcement actions are intended to respond to non-compliances at BNIs. The authority to implement escalating enforcement actions has been granted in the recent legislation including letters, monetary penalties, withdrawal of authorization, and incarceration. The specific tools to implement these actions have yet to be created or written. There does not appear to be a process for determining the relative significance of non-compliances other than the collective judgment of the inspector/regulatory authority staff. ASN requires the operator to take the necessary actions to correct identified deficiencies, comply with identified non-compliances, and to take actions to prevent recurrence. The inspection programme detects and requires corrective action for repeat

non-compliances, and stronger, although not clearly specified, enforcement actions may be taken. Corrective actions from previous non-compliances are routinely reviewed as part of the inspection programme. Currently, ASN staff members rely almost exclusively on softer approaches to compliance enforcement, which is not necessarily a negative approach. However, the lack of adequate enforcement tools is an area requiring some improvement. There appear to be some instances when agreements on corrective actions are decided in telephone conversations between ASN and the operator. These actions/requirements/expectations are not documented formally. It is not clear as to how these issues would be captured in the inspection programme for subsequent review, nor how they would be enforced if the operator did not complete them as agreed.

GS-R-1 §5.19

ASN issues letters to the operator following inspections that identify non-compliances. It appeared that minor issues or non-compliances might be corrected on the spot by the operator and not documented by the inspector in the exit meeting notes to the operator, the inspection letter to the operator, or in the inspection report. ASN relies on inspector skill and IRSN expert advice to determine whether an issue has only "minor safety significance." For issues identified to the operator as non-compliances in the formal documentation, the nature and basis of the non-compliance was identified. The period of time for the operator to respond to the inspection letter was standard (2 months from receipt of the letter, unless a major issue warrants immediate regulatory action). In some cases, correction of the non-compliance was expected earlier, and for longer term corrective actions, the action plan was expected to be included in the operator's reply to the inspection letter. No reasonable enforcement mechanism appeared available to ASN should operators fail to respond to the inspection letter within the required time frame.

GS-R-1 §5.20, 5.21

ASN, under the new law, has been delegated the statutory authority to order the operator to take the necessary actions to protect workers, the public, or the environment from imminent radiological hazards. Under the new law (Article 41), ASN also has the authority to revoke the authorization of the operator, with reinstatement being possible once the challenge to safety has been remedied to the regulator's satisfaction. Additionally, ASN has been delegated the authority to require actions from the operator to ensure safety, and may extend maintenance and refuelling outages to conduct additional inspections or justifications as required to ensure safety. These actions are subject to review by the Minister of Industry within 15 days of the decision by ASN.

GS-R-1 §5.22

The new law provides the authority for ASN to take enforcement actions and issue formal notices. The operator is informed of non-compliance decisions in writing according to ASN internal operating practices. Typically, following an inspection, a list of inspection findings is acknowledged, in writing, by the operator and the inspector, and this document is provided to the operator. A subsequent letter is issued by the associated DSNR identifying non-compliances and issues requiring corrective actions, requests for additional information, and observations. This letter is typically issued within 3 weeks of the completion of the inspection. The operator is expected to reply to the inspection letter within 2 months of the date of the letter describing what actions were taken or planned to correct the identified issues, to provide the information requested in the letter(or the plan for providing the information), and to discuss the observations described in the letter. The criteria for which issues would prompt the issuance of an enforcement formal notice letter (separate from the inspection letter) are not clear. As noted in the ASN self assessment and Recommendation RX above, the need exists to develop detailed implementing procedures for application of the enforcement programme.

GS-R-1 §5.23

With regard to the extent of enforcement authority delegated to inspectors to take on the spot enforcement actions, ASN has developed guidance that the individual inspector does not have the authority to take on the spot enforcement actions. If the inspector determines that immediate action is warranted, he/she would contact a higher authority individual within ASN (probably the DSNR director or sub directorate head). This policy is documented and was well understood by the inspectors interviewed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §5.18 states, in part, with regard to enforcement: *"The action shall be commensurate with the seriousness of the non-compliance."*

(2) **BASIS:** GS-R-1 §5.19 regarding issues of minor safety significance states, in part: *"In such circumstances, the regulatory body shall issue a written warning or directive to the operator which shall identify the nature and regulatory basis of each violation and the period of time permitted for taking remedial action."*

R16 **Recommendation:** ASN should provide guidance to the inspection staff on how to determine the relative seriousness or significance of non-compliances and how to resolve identified issues of minor safety significance, such that an appropriate and consistent level of enforcement action can be applied.

(1) **BASIS:** GS-R-1 §5.18 states, in part: *"Enforcement actions are designed to respond to non-compliance with specified conditions and requirements."*

R17 **Recommendation:** ASN should develop the necessary enforcement tools and implementation guidance to effectively and consistently implement enforcement sanctions commensurate with the seriousness of the non-compliance.

4.3.4 MEDICAL PRACTICES

Scope of inspection and enforcement for medical practices using radiation
GS-R-1 §5.12

ASN performs inspections of medical practices using radiation, primarily through the DSNRs.

A process has been set up to officially appoint inspectors, by Ministerial order, in radiation protection covering medical and biomedical practices, and industrial and research practices. There are both training and experience criteria. Applicants are considered by an internal ASN committee. An Order 13 September 2006 named 62 persons, the first to be named under the legal provisions. The IRRS team was informed that the TSN Act (2006-686, ART. 56-5º) restricts potential inspectors to ASN only.

The ASN inspection programme for the use of radiation in medical practices is part of the overall annual inspection plan. The ASN has developed a formal procedure for the development of this annual inspection plan (ASN/INS/01).

In planning the annual inspection programme, consideration is given to particular identified needs. This may be from feedback from previous inspection programmes, or advice received from IRSN. In 2006, facilities using X-rays in interventional procedures received particular attention.

In addition to inspections of medical practices using radiation, there are inspections on approved organizations, including those approved to provide technical controls in radiation protection. Inspections can occur prior to the approval and during the period of the approval. They may

involve visits to the headquarters of the organization or during operations at a site. The results of the inspections can influence the period of validity of the authorization for the approved organization.

However inspections of approved organizations performing the quality controls on medical devices required by the AFSSAPS decisions are performed by AFSSAPS inspectors. Given the crucial role of these quality controls in the radiation protection of the patient, AFSSAPS needs to utilize feedback from ASN inspections.

The conduct of inspections of medical practices using radiation
GS-R-1 §5.13:
ASN is developing internal guides for the conduct of inspections in nuclear medicine, interventional radiology, CT scanners, brachytherapy, external beam radiotherapy and blood irradiators. Three types of documents have been developed: *"Ordre du Jour"*, effectively the agenda for the inspection; *"Guide pour la conduite d'une inspection"*, giving in-depth detail for the conduct of the inspection; and *"Canevas"*, giving details for those activities that are under particular study. Once issued, these documents are used by the DSNRs to perform their inspections.

During the IRRS mission, one team member accompanied DSNR inspectors on three inspections – a nuclear medicine service at a large Paris Hospital; an interventional radiology and cardiology facility at another Paris Hospital; and an external beam radiotherapy facility in St Quentin, north of Paris. Based on the observations during these visits, together with the contents of the ASN inspection guides, it can be concluded that the inspection visits are well structured and professionally conducted, and cover the requisite items in *GS-R-1 5.13*.

The format of the inspections observed was: An initial meeting with the licensee, typically supported by the medical physicist (PSRPM), the radiation protection officer (PCR), a manager for the nursing and/or technologist staff, and, in the case of the nuclear medicine facility, an engineer with responsibilities for ventilation, sewage, etc. At this meeting the regulatory requirements associated with the ASN authorization of the facility were scrutinized and discussed, including other relevant authorizations (ARH, AFSSAPS), the qualifications and radiation protection training of key personnel (medical practitioners, medical physicists, RPO, MERs), the radiation protection plan, reports of regulatory controls (internal and external quality control, and radiation protection controls), personnel monitoring, and radiation protection of the patients. The meeting was followed by an inspection of the facility itself. An exit meeting was then held with the licensee, at which the inspector's findings, deviations and deficiencies were presented together with requests for correction.

ASN is careful to ensure that their inspections do not substitute for the responsibilities and activities of the licensee. As previously noted, the regulatory system places great reliance on approved persons and organizations performing controls, and one of the ASN inspector's role is to ensure that these have taken place as required. However one situation where the role of the ASN inspection may diminish the licensee's responsibility is with a pre-authorization technical visit. These occur for nuclear medicine, brachytherapy and external radiotherapy facilities. The potential problem arises when the ASN inspector performs technical measurements. Using the results of such measurements in the authorization process could shift the responsibility for safety to ASN. The regulatory body always has the right to perform any spot-checks, but to avoid problems with shifts in responsibility it is perhaps preferable to schedule a routine inspection soon after the facility has become operational.

The inspection programme for medical practices using radiation
GS-R-1 §5.14
Medical practices have been assigned to three broad bands:

- High frequency (every 3 years): external radiotherapy, nuclear medicine, brachytherapy;
- Medium frequency (every 6 years): interventional radiology, CT scanners;
- Low frequency (spot checks, as the programme allows): medical and dental radiology.

As noted above, in planning the annual inspection programme, consideration is given to particular identified needs. This may be from feedback from previous inspection programmes, or advice received from IRSN. In 2006, facilities using X-rays in interventional procedures received particular focus.

ASN is relatively new to the role of inspections in the medical field. Nevertheless, 215 visits were made to radiation users in medical practices in 2005.

France has had several major radiotherapy accidents in the last 2 years. Consideration should be given to more frequent regulatory inspections for this type of facility. It should be noted that discussions with SD7 suggested that they considered the current inspection frequency for radiotherapy facilities adequate, but indicated that they would be extending the scope of such inspections to include organizational and human factors as presented in the IAEA Safety Series Report 38. Analysis of data for inspections to radiotherapy facilities shows that these are actually occurring more frequently than the 3 year cycle.

High occupational doses and radiation injuries have been reported worldwide in many facilities that perform interventional X-ray procedures. Again consideration should be given to more frequent regulatory inspections to these facilities in France.

Types of inspections of medical practices using radiation
GS-R-1 §5.15:
ASN performs both announced and unannounced inspections of medical practices using radiation.

ASN does not use the services of consultants for its regulatory inspections of medical practices using radiation.

Inspections as a result of an abnormal occurrence in medical practices
GS-R-1 §5.16:
ASN does perform inspections as the result of an abnormal occurrence in medical practices using radiation. These have included inspections as a result of the accidents at radiotherapy facilities.

The role of ASN in these inspections is to gain detailed information about the accident for the purpose of being able to identify “lessons learned” so that these can then be passed on to all licensees and other relevant parties, plus feeding the findings back into the appropriate regulatory processes to minimize the likelihood of any recurrence of such an accident.

Reports of inspections of medical practices using radiation
GS-R-1 §5.17:
ASN inspectors are required to send a written follow-up letter to the licensee. This is normally done within 21 days, but may take up to 2 months if an additional letter has to be prepared.

The findings of the inspection are put into 3 categories – A. issues requiring correction action; B. request for additional information; and C. Observations.

Some analysis of inspection reports is performed and a working group has been formed to strengthen this activity. Results of the analysis will be incorporated into the regulatory process.

Enforcement actions with respect to non-compliance in medical practices
GS-R-1 §5.18 – 5.24:
ASN is still developing its enforcement policy in the area of medical exposures. The legal provisions are in place, but written formal enforcement policies and procedures to implement the provisions have yet to be developed.

Following the sending of the written inspection follow-up letter, the licensee has two months in which to respond detailing the set of actions he/she will take to address the non-compliances and other issues stated in the letter.

ASN asks for verification that corrective actions have been effected. Subsequent visits also act as a check on remedial actions.

Items of major non-compliance are referred by the DSNR inspector to DGSNR for guidance and a decision.

Current practice in ASN requires that the inspector refers to his/her supervisor or an ASN senior manager if an on-the-spot enforcement action is required.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §5.12 states *"Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations. In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator. Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements".*

G27 **Good practice**: Given that the regulatory system for radiation protection in medical exposures places significant reliance on approved persons and organizations performing radiation protection controls, it is commended that ASN has a system for inspecting the activities of such organizations, with feedback into their authorizations.

S30 **Suggestion:** That ASN ensures that AFSSAPS takes note of the findings of ASN inspections in the AFSSAPS processes for approval and inspection of organizations performing the quality controls on medical devices required by the AFSSAPS decisions.

(1) **BASIS:** GS-R-1 §5.13 states *"The main purposes of regulatory inspection and enforcement are to ensure that:*
(1) facilities, equipment and work performance meet all necessary requirements;
(2) relevant documents and instructions are valid and are being complied with;
(3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;
(4) deficiencies and deviations are identified and are corrected or justified without undue delay;
(5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate; and
(6) the operator is managing safety in a proper manner.
Regulatory inspections shall not diminish the operator's prime responsibility for safety or substitute for the control, supervision and verification activities that the operator must carry out.

G28 **Good practice**: ASN is to be commended for developing in-depth guidelines for the conduct of its inspections in medical practices using radiation.

S31 **Suggestion:** ASN is urged to complete the inspection documentation to cover all uses of radiation in medical practices (i.e. concerning conventional radiology and brachytherapy).

S32 **Suggestion:** That ASN but extends the scope of its radiotherapy inspections to include organizational and human factors as presented in the IAEA Safety Series Report 38.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S33 **Suggestion:** That ASN reconsiders the relative merits of inspectors performing technical measurements during a pre-authorization visit.

(1) **BASIS**: GS-R-1 §5.14 states *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*

R16 **Recommendation:** That ASN reconsiders the current frequencies for inspection of medical facilities using radiation, taking into account current international standards and good practice, in particular for interventional radiology and radiotherapy.

(1) **BASIS**:
GS-R-1 §5.17 states *"Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process."*

S34 **Suggestion:** ASN should complete the development of formal procedures to analyse inspection findings and to incorporate these findings into the appropriate regulatory processes.

(1) **BASIS**: (1) GS-R-1 §5.18 states *"Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance. Thus there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization. In all cases the operator shall be required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed time-scale, and to take all necessary measures to prevent recurrence. The regulatory body shall ensure that the operator has effectively implemented any remedial actions*

(2) **BASIS**: GS-R-1 §5.20 states *"If there is evidence of a deterioration in the level of safety, or in the event of serious violations which in the judgement of the regulatory body pose an imminent radiological hazard to workers, public or environment, the regulatory body shall require the operator to curtail activities and to take any further action necessary to restore an adequate level of safety."*

(3) **BASIS**: GS-R-1 §5.21 states *"In the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctioning at or damage to a facility, the regulatory body shall direct the operator to curtail activities and may suspend or revoke the authorization. The operator shall be directed to eliminate any unsafe conditions."*

(4) **BASIS**: GS-R-1 §5.22 states *"All enforcement decisions shall be confirmed to the operator in writing."*

(5) **BASIS**: GS-R-1 §5.23 states *"The extent of the authority of the regulatory inspectors to take on the spot enforcement actions shall be determined by the regulatory body."*

(6) **BASIS**: GS-R-1 §5.24 states *"Where on the spot enforcement authority is not granted to individual inspectors, the transmission of information to the regulatory body shall be suited to the urgency of the situation so that necessary actions are taken in a timely manner; information shall be transmitted immediately if the inspectors judge that the health and safety of workers or the public are at risk, or the environment is*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
endangered." R17 **Recommendation:** That ASN develops and implements a formal enforcement policy that covers the use of radiation in medical practices.

4.3.5 INDUSTRIAL AND RESEARCH PRACTICES

Scope of inspection and enforcement for industrial and research practices
GS-R-1 §5.12
As a result of documentation seen, discussions held with personnel of the Nuclear Safety and Radioprotection Division (DSNR) of ASN at Nantes (within the local DRIRE: Direction Regionale de l'Industrie, de la Recherche et de l'Environment des Pays de Loire) and participation as an observer in three regulatory inspections[3], the IRRS team concluded that this DSNRof ASN complies with this section of GS-R-1.

It should be noted that the scope of inspections includes veterinary practices: both diagnostic and therapy uses of radioactive sources in animals (namely horses, cats and dogs), and the use of electrical generators in veterinary applications, mainly in radiography studies.

No recommendation or suggestion is made.

The conduct of inspections of industrial and research practices
GS-R-1 §5.13:
The DSNR at Nantes complied with this section of GS-R-1. Inspection and enforcement activities verify and ensure compliance with all requirements. The assessment of the competence of operator's contractors is not a function of the DSNR but the safety-related services provided to the operator must be carried out by approved organizations.

The inspectors inform the operator's counterpart at the end of the inspection of any identified good practices and corrections required for detected deficiencies and deviations. After the inspection a follow-up letter is sent setting out a time period of two months, within which the licensee must respond with a proposed corrective action plan for the items of non-compliance. For urgent issues of non-compliance, ASN requests immediate action, plus post-inspection verification at the site (*Guide sur la demarche d'inspection*, ASN/INS/02a, 01/10/2005).

Lessons learned are disseminated inside ASN and to operators by means of the internet, e-mails and letters. The prime responsibility for safety of the operator is not diminished by the regulatory inspections carried out by the DSNR.

The inspection programme for industrial and research practices
GS-R-1 §5.14
The IRRS team found that this DSNR of ASN complied with this requirement. No recommendation or suggestion is made.

Types of inspections of industrial and research practices
GS-R-1 §5.15 – 5.16:
The IRRS team found that this DSNR of ASN complied with these requirements. No recommendation or suggestion is made.

[3] Gammagraphy tasks performed by personnel of APAVE in the workshop of MATAL S.A. located in Nantes (unannounced), gammagraphy practices performed by l'Institut de Soudure Services (Agence de Donges) in the Total's Refinery located in Donges (unannounced), and in the IONISOS industrial irradiator (a basic nuclear installation) located in Sablé (announced).

ASN performs both announced and unannounced inspections of industrial and research practices using radiation. ASN also performs inspections as the result of an abnormal occurrence in industrial and research practices using radiation.

For the inspection performed at the industrial irradiator the Division used the services of IRSN on site[4] but regulatory responsibility was maintained by ASN.

Reports of inspections of industrial and research practices
GS-R-1 §5.17:
The IRRS team found that this DSNR of ASN complied with these requirements. No recommendation or suggestion is made.

Enforcement actions with respect to non-compliance in industrial and research practices
GS-R-1 §5.18 – 5.24:
As noted above, after the inspection the DSNR sends a follow-up letter setting out a time period of two months, within which the licensee must respond with a proposed corrective action plan for the items of non-compliance. For urgent issues of non-compliance, the DSNR requests immediate action.

Inspectors do not have the authority for taking on the spot enforcement actions, they must inform ASN authorities.

There is written guidance ("*Guide sur la demarche d'inspection*", ASN/INS/02a, section 7.12), however a more detailed guide or procedure for inspectors detailing how to proceed accordingly is necessary.

No recommendation or suggestion is made.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 *§*5.13, "*The main purposes of regulatory inspection and enforcement are to ensure that:*
(1) facilities, equipment and work performance meet all necessary requirements;
(2) relevant documents and instructions are valid and are being complied with;
(3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;
(4) deficiencies and deviations are identified and are corrected or justified without undue delay;
(5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate;
(6) the operator is managing safety in a proper manner.
Regulatory inspections shall not diminish the operator's prime responsibility for safety or substitute for the control, supervision and verification activities that the operator must carry out."

G29 **Good Practice:** a) The preparation of inspections prior to their execution; and, b) the explanations and information provided by ASN inspectors to the operator at the end of inspections on identified good practices and deficiencies or deviations.

(1) **BASIS:** GS-R-1 *§*5.24, "*Where on the spot enforcement authority is not granted to individual inspectors, the transmission of information to the regulatory body shall be suited to the urgency of the situation so that necessary actions are taken in a timely*

[4] One member of the Institute was present during the inspection (as well as one of SD 3 Fontenay-aux-Roses).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
manner; information shall be transmitted immediately if the inspectors judge that the health and safety of workers or the public are at risk, or the environment is endangered."
R18 **Recommendation:** ASN should prepare more detailed guidance or procedures addressed to inspectors establishing in writing how they must proceed.

4.3.6 WASTE FACILITIES, DECOMMISSIONING AND REMEDIATION

Discharge Control

GS-R-1 §5.12, 5.14, 5.15; SS115, III.3, III.9-13; WS-R-2 5.8

Discharge and environmental monitoring inspections are part of the programme of approximately 750 planned inspections carried out at BNIs each year. Effectively, this means approximately 3 inspections per plant every 2 years in the discharge/environment field, often with different kinds of samples taken. Not all inspections are announced. During inspections observed by the IRRS team at an EDF nuclear power plant (Nogent-sur-Seine) and at the Centre de l'Aube waste repository, the inspector demonstrated a high level of competence, and the inspection was well conducted.

A number of discharge limitation criteria have been established against which performance is judged. Non-compliance with such criteria has to be declared publicly by the operator and the operator has to provide an assessment of causes and effects within two months.

Inspection of BNIs is largely carried out by the regional offices. For the large number of non-BNIs under ASN authority, the control is organized on two different levels. Some approved organizations under ministerial agreement (approximately 40) carry out some technical controls. The performance of these contracted organizations is regularly verified by ASN.

ASN has the overall responsibility for coordinating the actions relating to environmental monitoring. IRSN also takes a leading role in conducting such activities. This includes the operation and maintenance of four networks for remote monitoring of radiation levels in the country. The Téléray network (180 stations nation-wide) continuously monitors gamma activity; measurements are recorded every 4h unless the detector signals an alert of elevated radiation levels. In addition, remote monitoring takes place through aerosol sampling (the SARA network), through monitoring of activity in river water downstream of installations (the Hydrotéléray network) and through monitoring of activity in water treatment plants and hospital wastewaters (the Téléhydro network). In all, these networks comprise 210 measuring points distributed over the country.

Environmental and discharge monitoring is performed on a large scale by the installations. Duplicate samples are taken, with IRSN performing independent analyses. The number of such analyses carried out by IRSN amount to about 100 000 per year, out of which around 30% are performed for the purpose of quality control Much of the environmental monitoring data is accessible to the public via the Internet.

For installations other than BNIs, the licensees are required to establish a plan for the management of radioactive waste and effluents which must comply with criteria established by the Circular DGS/DHOS of 9 July 2001. The licensee is required to monitor the discharges of radioactive effluents and to record the report of the monitoring. ASN inspectors review the records during their inspections.

Chronic Exposure & Remediation

SS115 VI; WS-R-3, 3.1, 5.2, 5.5, 5.7

The guide DGS/DPPR of October 2000 established a methodology to assess the impact of the situation, characterize the potential remedial situation and the associated benefits of possible remedial measures. The Circular of 16 May 1997 on the administrative procedure for polluted sites contaminated with radioactive materials requires that a control is carried out by IRSN after the remediation to verify that the objectives established by the ministry of Health (now by ASN) are reached. Given the 2006 legislation regarding Safety and Transparency in the nuclear field, ASN might consider reviewing and updating this regulation.

There is no clear method established for how ASN or other local authorities verify compliance of remediation activities for different type of facilities with criteria previously approved by ASN. The guide DGS/DPPR of October 2000 requires that the goal for remediation shall be established as the reference levels for remediation. The guide SD3-D-06 of 16 July 2006 requires that the management of radioactive waste shall be prepared taking into account ANDRA's recommendations. An evaluation of the end state can be conducted by IRSN which submits the results of the evaluation to ASN. The circular of 16 May 1997 on the administrative procedure for polluted sites contaminated with radionuclide requires specific actions be taken if the OPRI (now IRSN) report concludes that the site needs new remediation or investigation. In that case, easement can be established to document and maintain a legal record of the contamination details.

Decommissioning

GS-R-1 §5.14, 5.15, 5.17, 5.18; WS-R-2 6.1-6.13

For inspection and enforcement of waste facilities, decommissioning and remediation activities ASN applies the same regime as it does for other BNIs. The inspection programme of waste facilities, decommissioning and remediation activities is well managed. A yearly progamme is developed by ASN headquarters together with the regional offices (DSNR) and includes both announced and unannounced inpections. The frequency of the inspections is commensurate with the magnitude and nature of the potential hazards. The inspections are normally carried out by two regional inspectors, one technical support person from IRSN and one member of ASN-SD3. The inspections are extremely well prepared and carried out effectively and efficiently. The findings of earlier inspections and corrective actions are thoroughly followed-up. The inspectors prepare reports of the inspections on which the operator has to react within given time frames.

Enforcement actions are taken commensurate with the non-compliance observed. The enforcement power of ASN has been considerably increased by the 2006 law on transparency. At the time of the IRRS mission there has not been enough experience aquired with new instruments (i.e. fines) in the decommissioning area to be assessed by the mission.

Occupational radiation protection

GS-R-1 §5.15; SS115 I

Observations were made by IRRS team members during occupational radiation protection inspections at the EDF site in Nogent-sur-Seine and the ANDRA Centre de l'Aube facility. The installations have a Radiation Protection Service which is responsible for the execution of the activities identified in the Safety Report Analysis and which was approved by ASN. The team of inspectors was competent and the occupational radiation protection inspection programme appeared to be well implemented in BNIs.

The Safety Report Analysis that the licensee has to present to ASN for approval contains a chapter (Chapter 9) that addresses the Radiation Protection Service and its obligations. The content is consistent with the requirements of BSS and the Safety Requirements of RS-G-1.

For nuclear power plants, an average of one inspection per year is focused on occupational radiation. For the Centre de l'Aube facility there is one every third year. However, the inspectors can make observations regarding radiation protection when performing inspections targeting other areas.

4.4 REGULATIONS AND GUIDES

This section considers regulations and guides for each of BNIs, medical practices, industrial and research practices and waste facilities, using the requirements of GS-R-1, listed here, as the basis. The text references GS-R-1 as applicable.

GS-R-1 Sections §5.25- 5.28
GS-R-1-1 §5.25

In France, the regulatory pyramid for nuclear safety and radiological protection is comprised of:

- Laws, of which there are two directly related to these matters: 1) The Law 61-842, concerning atmospheric pollution and malodour control, of August 2nd, 1961, and 2) Law 2006-686 on "Transparency and Security in the Nuclear Field", approved on June 13th, 2006.
- Decrees develop the administrative requirements of the laws. A number of decrees have been issued or planned to be issued as explained in Chapter 1 of this report. Decrees are also issued for authorizing the creation of a nuclear installation.
- Ministerial Orders develop, in more detail, the content of the Decrees.
- Ministerial Circulars describe how to implement Ministerial Orders.

Orders and Circulars, signed by the Ministers competent on the matter, complement the Laws and Decrees. They are mandatory and establish the body of regulations for nuclear safety and radiological protection.

Additionally, some 40 "Fundamental Safety Rules" (FSR) have been issued to reflect the technical position of ASN about a variety of matters related to nuclear safety and radiological protection. For example:

- RFS 2002-1 "Development and Utilisation of Probabilistic Safety Assessment", in Pressurised Water Reactors.
- RFS V.2.c "General Rules Applicable to the Manufacture of Mechanical Materials", in Pressurised Water Reactors (Rev. 1, 1986)
- RFS I.3.C "Criticality Risks" (1984)

The FSR are not mandatory, but they present methods that ASN considers acceptable to fulfil current requirements. They constitute what are generally referred to as safety guides.

Industry Standards have been elaborated by industrial associations, such as the "French Association for the Rules on the Conception and Construction Materials for Nuclear Electric Boilers". There are a number of such standards regarding various topics such as the RCC-M and RCC-E dealing, respectively, with mechanical and electrical elements of the nuclear island, or the RCC-C dealing with nuclear fuel. These standards are only acceptable when the ASN issues a FSR endorsing them.

France has 58 NPP in operation and a large nuclear industry. However, all the plants belong to one utility, Electricite de France (EDF), that is state owned, as are the operators of most nuclear installations, e.g., AREVA has developed and operates the factories for uranium enrichment, fuel fabrication and reprocessing.

In many areas, the fact that the regulator interacts with only one company for each major activity (NPP operation, fuel making, etc.) has led to not issuing public standards indicating acceptable methods for performing some important activities. Letters sent directly between ASN and the licensee have served as the reference and established acceptable standards.

Further development of the regulations and guides for NPPs is planned by ASN in the framework of the project for "Harmonisation of Reactor Safety in WENRA Countries", with WENRA being the Western Europe Nuclear Regulators Association. The proposed deadline to complete the project is 2010. As presented at the November 2006 WENRA meeting, the project calls for issuance of a Ministerial Order and ASN development of guides regarding these orders for each of the following subjects:

- Policy and Management of Safety
- Safety Approach
- Design of Pressurized Water Reactors
- Operation of Pressurized Water Reactors

Besides, it is planned to review and prepare regulations, if necessary, regarding protection against internal fires and on-site emergency preparedness for nuclear installations.

The WENRA project is a systematic approach to systematize the review of present regulations and guides for NPPs that is expected to produce a consistent set of requirements and guides. However, the team has identified the need to perform also a systematic review of regulations and guides for the facilities and activities outside of the NPP regulatory envelope.

GS-R-3 "The Management System at Facilities and Activities", published in 2006, describes the characteristics of a comprehensive management system based on safety as its fundamental principle. Although the Order of August 10th, 1984 concerning Quality of Design, Construction and Operation of BNIs contains requirements that address some aspects of management systems, ASN has not required incorporation of all the requirements of GS-R-3 at BNIs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1, §3.2 states: "*... the regulatory body (1) shall establish, promote or adopt regulations and guides upon which its regulatory actions are based*"

R19 **Recommendation**: ASN should undertake a project to review in a systematic way the present requirements and guidance for facilities and activities other than NPP, in order to produce a more consistent assembly of regulations.

(1) **BASIS:** GS-R-3 §2.5 states: *"The management system shall be used to promote and support a strong safety culture"*

(2) **BASIS:** GS-R-3 §3.10 states *"Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate process at various levels of the organization"*

(3) **BASIS:** GS-R-3 §5.27 states: *"Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
(4) **BASIS:** GS-R-3 §5.28 states: *"Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified"*
(5) **BASIS:** GS-R-3 §5.29 states: *"The implementation of such changes shall be planned , controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised"*
(6) **BASIS:** GS-R-3 §6.1 states: *"The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the internal results and to identify opportunities for improvement"*
(7) **BASIS:** GS-R-3 §6.2 states: *"Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture"*
R20 **Recommendation:** ASN should issue a generic requirement to facilities and activities to establish a management system, graded according to the safety significance and complexity of the facility and/or activity.

4.4.1. NUCLEAR INSTALLATIONS

GS-R-1-1 §5.25, 5.26, 5.27, 5.28

Law 2006-686, "Transparency and Security in the Nuclear Field," contains progressive dispositions, such as in the Article 29.III, referring to nuclear installations, that state "The licensee of a basic nuclear installation carries out periodic safety reviews of his installation by taking account of the best international practices. This periodic review must allow the situation of the installation to be appreciated with regard to the rules applying to it and must make it possible to update the assessment of risks or drawbacks the installation presents for the interests mentioned in I of Article 28, by taking account in particular of the state of the installation, the experience learned from operation, and the evolution of knowledge and of the rules applying to similar installations. The licensee sends the Nuclear Safety Authority and the ministers tasked with nuclear safety a report including the conclusions of this review and, where applicable, the provisions it envisages taking to remedy the observed anomalies or to improve the safety of his installation.

After analysing the report, the Nuclear Safety Authority can impose new technical prescriptions. It sends the minister tasked with nuclear safety its analysis of the report."

This means that the new law allows ASN to impose additional safety prescriptions to licensees that already hold an authorization thereby increasing the safety level of the installation.

At each Periodic Safety Review (PSR), ASN verifies that the installation continues meeting the standard of the current license and informs the licensee which subjects require special attention and that certain improvements are requested. The selection of the subjects needing additional addition or improvement is the result of a process of analysis that takes into account operating experience and the current state of the art. The Advisory Group for Reactors participates in this process to provide its opinion regarding the selection of subjects.

ASN has issued letters to all nuclear facilities containing the technical requirements that shall fulfill the process of modifications. The letter includes the definition of the rating of modifications

according to the safety significance of the modification and establishes the process for its authorization taking into account that rating, as well as what information to send to ASN regarding the modification.

The FSR 2002-1 "Development and Utilisation of Probabilistic Safety Assessment", in Pressurised Water Reactors, details acceptable methods for developing PSA studies, although there is no requirement perform a PSA.

ASN requests a PSA, with a given scope, for each NPP in the letter sent to each licensee about the scope of each Periodical Safety Review (PSR). For nuclear installations other than NPP, PSAs are not requested. However, for specific cases, e.g. the crane that handles irradiated fuel at a facility of COGEMA in La Hague, a probabilistic safety study has been performed to better analyse the risks associated with a given activity, and that analysis is documented in the Safety Analysis Report.

For future reactors, the "Technical Guidelines for the Design and Construction of the Next Generation of NPP with Pressurized Water Reactors" contains the following instruction: "probabilistic safety assessment has to be performed with the following objectives at the design stage: supporting the choice of the design options, (…), appreciation of the improved safety level compared to existing plants"

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: NS-R-2 "Safety of Nuclear Power Plants: Operation", Section 10 discusses periodic safety review (PSR), describes the need for and the scope of the PSR; it is further developed in Safety Guide NS-G-2.10 "Periodic Safety Review of Nuclear Power Plants"

(2) **BASIS**: Draft Safety Requirements (DS 316, draft dated 24 August 2006) "Safety of Fuel Cycle Facilities", §2.17. states *"The operating organization shall carry out at regular intervals periodic safety reviews of the facility to ensure that the safety case remains fully valid and that modifications made to the facility, as well as changes in its operating arrangements or utilization, are accurately reflected"*

G30 **Good Practice:** The Law 2006-686 on "Transparency and Security in the Nuclear Field", through the instrument of the periodical safety review establishes a method for requesting improvement in the safety level of the installation.

S35 **Suggestion:** That the scope, content and process of PSR, currently reflected in part in direct letters addressed by ASN to the utilities be described in an appropriate requirement or guidance.

(1) **BASIS**: NS-R-2 "Safety of Nuclear Power Plants: Operation", Section 7 states "*Plant Modifications", describes which modifications are scoped and the need for establishing a process for its authorization and control, further developed in Safety Guide NS-G-2.3 "Modifications to Nuclear Power Plants",*

(2) Draft Safety Requirements (DS 316, draft dated 24 August 2006) "Safety of Fuel Cycle Facilities", §9.35 states: *"The operating organization shall establish a process whereby its proposals for changes in design, equipment, feed material characteristics, control or management are subject to a degree of assessment and scrutiny appropriate to the safety significance of the change (...)".*

R21 **Recommendation:** ASN should formalize through appropriate guidance the spelling out of acceptable criteria for the process of modifications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: NS-R-1 "Safety of Nuclear Power Plants: Design", **§**5.69 states: *"A safety analysis of the plant design shall be conducted in which methods of both deterministic and probabilistic analysis shall be applied".*

(2) Draft Safety Requirements (DS 316, draft dated 24 August 2006) "Safety of Fuel Cycle Facilities", **§**2.7 states: *"The design features, controls and arrangements necessary to implement the defence in depth concept shall be identified mainly through a deterministic analysis (which may be complemented with probabilistic studies) of the design and operational regime.". ."* IAEA Safety Guide GS-G-1.2 on Review and Assessment of Nuclear Facilities by the Regulatory Body in Article 3.59 states that *"As a complement to the deterministic approach, the regulatory body should require an evaluation of the risks arising from the facility. A common method of providing such an evaluation is for the operator to perform a probabilistic safety assessment (PSA)."*

S36 **Suggestion:** A general policy for the utilization of PSA or probabilistic studies, as applicable with a graded approach, should be established at nuclear installations and the corresponding guidance should be elaborated and published.

4.4.2 NUCLEAR POWER PLANTS (NPP)

GS-R-1-1 §5.28

The analysis of operational experience and the feedback of the lessons learned is widely recognized as one of the most powerful methods for preventing accidents and improving the safety of the plant. The Order of August 10th, 1984 concerning Quality of design, Construction and Operation of BNI requires the analysis of events to obtain the root causes. However, there are some elements that are not addressed as a requirement or as a fundamental safety guide, e.g. screening of events at a national level or trending analysis. ASN has identified this need and is presently reviewing its requirements on this matter.

In practice, at the Periodic Safety Review, severe accidents is one of the subjects explicitly and broadly addressed, although there is no requirement or guidance that covers this important subject.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: NS-R-2 *"Safety of Nuclear Power Plants: Operation". §2.22 states: "Similarly, the operating organization shall obtain and evaluate information on operating experience at other plants to derive lessons for its own operations*". This requirement is further developed in Safety Guide NS-G-2.11 "A System for the Feedback of Operational Experience from Events in Nuclear Installations", that contains guidance such as following:

- Section 3 dealing with: "Screening of events" states (in **§**3.10) the need for *"screening at the national level" of events;*
- Section 6 dealing with: "Trending and Review to Recognize Emergent Problems" spells out a number of issues, e.g., discusses (in **§**6.2) the usefulness of a trending programme *"to identify an abnormal trend early enough (...) to prevent a significant event"*

S37 **Suggestion**: ASN should complete its present process of producing regulations and guides on analysis of operational experience.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: NS-R-1 "Safety of Nuclear Power Plants: Design", §2.7 states *"In order to achieve these three safety objectives, in the design of a nuclear power plant, a comprehensive safety analysis is carried (...). The safety analysis examines: (...) event sequences that may lead to a severe accident."*

S38 **Suggestion:** That what is presently requested to the operating NPP regarding the severe accident is described in an appropriate requirement or guidance.

4.4.3 MEDICAL PRACTICES

System of regulations and guides for medical practices

GS-R-1 §5.25:

The regulations applicable to the uses of radiation in medical practices have been issued by the Ministers of Health and Labour. These regulations provide further detail to the legislative parts of the Public Health Code and the Labour Code, and are codified in the regulatory parts of these respective Codes. From these regulations, many ministerial orders have been issued providing further detail, particularly on implementation. With the enactment of the TSN law, ASN will be able to issue technical decisions. In addition some circulars have also been issued.

As noted elsewhere in this report, the set of regulations, orders, decisions and circulars is somewhat fragmented and, as a consequence, it is understandable why it might be difficult for a licensee to understand all their regulatory obligations.

Purpose of the regulations with respect to medical practices

GS-R-1 §5.26

In the context of medical exposures, the regulations in France provide a framework for ministerial orders and decisions and these provide the detailed technical requirements rather than through detailed requirements incorporated into individual authorizations.

Guides with respect to medical practices

GS-R-1 §5.27:

ASN is preparing guidance for users of radiation in medical practices on how to comply with the regulatory requirements. To date such guidance has been issued to nuclear medicine practices and a draft has been prepared for radiologists and dentists. All forms for declaration and authorization for medical practices using radiation also contain guidance.

Professional societies are preparing guidance on justification and optimization. For example, the French Radiological Society, with the cooperation of ASN, has produced guidance on the good use of medical imaging examinations, addressing justification.

Regulations and guides – operational feedback and international standards with respect to medical practices

GS-R-1 §5.28:

ASN has created an in-house working group called the *"Mission RadioProtection des Patients"* (MRPP), with membership from ASN Deputy General Directors, SD7, a representative from each DSNR and invited experts. MRPP, among other functions, will analyse the results of inspections with respect to radiation protection of patients. The results of this analysis will be fed back into the regulatory programme.

ASN has also established an action plan (PASEPRI) to assess the impact of medical exposures in France. Such information is currently lacking for France, and once obtained will provide input into the regulatory framework. ASN is collaborating with IRSN and InVS. Some preliminary results have been presented following analysis of initial data by these bodies.

ASN actively seeks input from professional societies when developing guidance.

As noted elsewhere in this report, ASN should also consider the safety standards and guidance published by the IAEA.

As noted elsewhere in this report, ASN should also consider the safety standards and guidance published by the IAEA. ASN plans to extend its inspection in radiotherapy for assessment of organizational and human factors, according to the latest IAEA safety guidance in radiotherapy (Safety Report Series No. 38).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §5.25 states *"The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales."*

S39 **Suggestion:** ASN should use its new powers to issue a set of technical decisions, after appropriate consultation and review, to give a coherent and harmonized set of regulatory requirements for authorized and declared practices using radiation for medical exposures based on current international standards such as those of the IAEA.

(1) **BASIS:**
(1) GS-R-1 §5.27 states *"Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator."*

(2) **BASIS:** GS-R-1 §5.28 states *"In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."*

R22 **Recommendation:** That ASN completes the development of guidance on regulatory compliance for all areas of radiation use in medical practices. That the ASN should also consider the IAEA safety standards and guidance when developing regulations and guides.

4.4.4 INDUSTRIAL AND RESEARCH PRACTICES

System of regulations and guides for industrial and research practices
GS-R-1 §5.25:
A system of regulations and guides is in place for industrial and research uses of radiation. ASN is preparing a draft of an amended version of the Public Health Code. In the domain of industry and research, this will introduce authorization for the distribution of electrical generators of ionizing radiation (other than electron microscopes), and expand the existing rules for the deregulation (*"déclassement administratif"*) of a radioactive sealed source. The preparation of this draft is well advanced and once in force, these gaps in the regulatory role of ASN will be filled.

Guides with respect to industrial and research practices

GS-R-1 §5.27:

Good examples of guidance are Guide ASN/INS/02a *"Guide sur la demarche d'inspection"* Rev. 3 issued by SD 4 (01/10/2005), Note n° SD3-D-08 *"Démarches à effectuer en vue d'assurer l'élimination des sources radioactives scellées inutilisées ou périmées"* Rev. 0 issued by SD 3 (26/10/2005) and the so called *"Canevas"* concerning, *inter alia*, inspection (available on the ASN intranet).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** (1) GS-R-1 *§*5.25 states "*The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales.*"

BASIS: GS-R-1 *§*5.26 states "*The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.*"

BASIS: GS-R-1 *§*5.27 states "*Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator.*"

BASIS: GS-R-1 *§*5.28 states "*In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA Safety Standards.*"

G31 **Good Practice:** The regulatory activities performed by SD1 with respect to industry and research are covering these sections of GS-R-1.

4.4.5 WASTE FACILITIES, DECOMMISSIONING AND REMEDIATION

GS-R-1 §5.25; WS-R-1; WS-R-2; WS-R-3

The regulation of the management of radioactive waste from BNIs (Basic Nuclear Installations) is structured within a framework defined by a Ministerial Order of 31 December 1999 stipulating the general technical regulations intended to prevent and limit the detrimental effects and external hazards resulting from the operation of BNIs. In particular this ministerial order requires a study (called "waste study") describing how the waste produced in BNIs is managed. The guide SD3-D-01 of 23 September 2002 requires that the licensee describe the links with the disposal routes. One part of this study (the referential) is to be approved by the ASN.

The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes, defines the National Policy for the Management of Radioactive Materials and Wastes, the organization and funding of the management of radioactive materials and wastes and controls and sanctions. This Programme Act considerably strengthens the legal framework in the field of radioactive waste management. ASN still has to develop several decrees and orders to fully implement the new framework. In addition much work is underway at ASN to identify and refine the technical guidance needed. Many guides are under development within the WENRA project which aims to make the requirements of the IAEA Safety Standards obligatory for all WENRA members.

ASN establishes the regulatory requirements in the field of radioactive waste management including disposal facilities, and controls such activities, requires corrective measures, and can require an activity be stopped if safety problems are identified.

Radiation Protection

GS-R-1 §5.25, 5.26, 5.27; SS115 I

For Workers:

The new articles R. 231-71 to R. 231-116 of the Labour Code, introduced by decree 2003-296, create a single radiation protection system for all workers (whether or not salaried) likely to be exposed to ionizing radiation during their professional activities. Of these requirements, the following should be mentioned:

- Application of the optimization principle to the equipment, processes and work organization (art. R. 231-75) which will lead to clarification of where responsibilities lie and how information is circulated between the head of the facility, the employer (particularly when he or she is not the head of the facility) and the person with competence for radiation protection.
- Dose limits (art. R. 231-76) were reduced to 20 mSv for 12 consecutive months, barring waivers resulting from exceptional exposure levels justified in advance or emergency occupational exposure levels.
- Dose limits for pregnant women (art. R. 231-77), or more accurately for the child to be born, were established at 1 mSv for the period from the declaration of pregnancy up until birth.

For Public:

SS115 III

The effective annual dose limit (art. R. 1333-8 of the Public Health Code) received by a member of the public as a result of nuclear activities is set at 1 mSv; the equivalent dose limits for the lens of the eye and for the skin (average value for any 1cm2 area of skin) are set at 15 mSv/year and 50 mSv/year respectively. The calculation method for the effective and equivalent dose rates and the methods used to estimate the dosimetric impact on a population are defined by Ministerial Order of 1 September 2003.

The Basic Safety Rule RFS III.2.f, concerning a deep geological disposal facility specifies that "individual dose equivalents must be limited to 0.25 mSv/year for extended exposure associated with events which are certain or highly probable". This RFS adds that "this value corresponds to a fraction of the annual limit of exposure of the public in a normal situation". ANDRA also adopted a fraction of the annual limit of exposure of the public for the near surface repositories.

There are no other dose constraints established in the regulatory framework in relation to the optimization of both the public and the worker exposures.

The review team was informed that the optimization principle from the radiation protection point of view, is required by the Public Health Code (Art. L. 1333-1). Furthermore, each activity involving radioactivity should be first justified, noting that radioactive waste management is a consequence of practices that have been justified. The pathway for the management of radioactive waste (pre-treatment, treatment and disposal) shall be authorized by the regulator like any BNI, or at least, like ICPE (Installations Classified for Protection of the Environment) or according to the Public Health Code rules. Optimization is evaluated on a case by case basis. The National Plan for the Management of Radioactive Materials and Wastes has to verify the consistency of the different waste streams and pathways taking into account the desire for optimization.

The optimization of safety measures and radiation protection is assessed during the licensing process. Before granting any BNI's authorization, ASN requires the licensee to provide, in its

safety report, an analysis of the optimization of the radiation protection measures taken or planned in the facility (note DSIN-FAR/SD3/n°50 208/01 of 3 April 2001 on the content of the safety report for non-reactor and non-disposal installations).

The guide DSIN-FAR/N°A/11862/92 of 18 May 1992 on the establishment of General Operating Rules requires the licensee of non-reactor installations to establish local rules and procedures necessary to ensure an appropriate level of safety, especially (4.2.6.) for the management of radioactive waste. The same guide requires that the licensee explain provisions undertaken to comply with the legal requirements for radiation protection (4.2.10).This guide also requires the operator to provide elements on specific provisions regarding activities in controlled areas from the radiation protection perspective, especially the protective equipment. The Ministerial Order of 10 August of 1984 requires that operations related to the safety of the installation are accomplished by qualified staff, that operations are properly recorded, and that non-compliances with requirements are reported. The Public Health Code requires that some areas be classified for protection against ionizing radiation. An order of 15 May 2006 establishes the rules to classify these areas. The Public Health Code also requires the utilization of appropriate monitoring devices. The ASN verifies the implementation of these requirements through both the authorization process and current inspection practice.

General safety provisions

GS-R-1 §5.25, 5.26, 5.27; SS115 2.23-2.26; Schedule II, App I.III; WS-R-2, 5.5-5.8, 2.2-2.7, 3.5, 5.15; WS-R-1 4.1-4.9

In the field of radioactive waste management, the operators define their general strategy and programmes which are periodically reviewed and assessed by ASN (and its technical supports). The operators also produce a "waste study" which is submitted to the ASN for review and approval (the "referential" part must be approved by the ASN). The nuclear operators are responsible for the environmental protection during all stages of their nuclear installations and, among them, of their predisposal facilities (treatment, storage, etc.).

Notably the operator of a BNI has to comply with the following requirements:

- the procedures for authorization of creation of a facility, including a public inquiry procedure. The technical dossier includes an impact study, a safety assessment, and, in case of releases, a document to the European Commission,
- the technical requirements imposed on the operator and issued by ASN as an accompaniment to the authorization decree,
- the procedures for the commissioning of the installation,
- a periodic revision of the safety assessment of the installation (to be submitted to ASN),
- the procedures for the decommissioning of the installation,
- declaration of incidents,
- the production of an annual report transmitted to the Local Information and Follow-up Committee and the High Committee for Transparency and Information on Nuclear Safety required by the recent law.

The Ministerial Order of 10 August of 1984 requires the licensee to establish organizational arrangements to ensure an adequate level of quality of operations important to safety. The guide DSIN-FAR/N°A/11862/92 of 18 May 1992 on the establishment of General Operating Rules requires that the licensee establishes safety procedures. The decree of 11 December 1963 requires the licensee to provide an Internal Emergency Plan, and to test this Plan periodically. The guide DSIN-FAR/SD3/n°50 208/01 of 3 April 2001 on the content of the safety report for non-reactor

and non-disposal installations requires the operator to provide the description of monitoring equipment (I.4). The decree of 4 May 1995 and the order of 26 November 1999 require that the licensee implement an appropriate environmental surveillance programme with the proper monitoring equipment, assess the public exposure, and to take and maintain adequate records of the discharges of radioactive effluent.

There is a classification system for radioactive waste, although not established by regulations. The classification system is based on 2 parameters regarding the radioactive content of the waste:

- activity level
- half-life of the radionuclides contained in the waste.

This system and the radioactive waste management routes (existing or under study) are linked.

The Ministerial Order of 31 December 1999 requires the licensee to record and annually report the inventory of radioactive waste in its possession to ASN. This information provides input to a National Inventory of recoverable materials and radioactive waste. Prior to 2002 the inventory report only included the existing waste and their location. In 2004, to comply with a Government requirement, the National Inventory report added forecasts, totaling (by category), and described the radioactive waste in the form of a hundred "radioactive waste families" with each "family" being allocated to one of the 5 categories of the French waste classification (HLW, ILW-LL, LLW-LL, LILW-SL, VLL). This inventory, which was updated in 2006, will be revised every 3 years in the future (see the 2006 Law on Transparency and Safety in the Nuclear Field). The inventory was carried out by ANDRA in liaison with the waste producers. ASN participates in the steering committee in charge of the objectives and general supervision of this inventory.

The French regulation on radiation protection concerning radiation protection of the public (Public Health Code) applies to every nuclear activity and includes the entire decommissioning process. In the case of a facility released with restrictions on future use, restrictions are legally recorded with a notary to make sure future owners will be informed of them. If radiation emission on the site is too high to guarantee the protection level of the public after decommissioning, ASN can have the operator keep the site as its own property and not release it until the radiation level has decreased sufficiently to allow release.

The decommissioning process has to comply with the regulation on radiation protection for workers and for the public. In fact, this regulation deals with nuclear activity and not directly with facilities. In this way, the decommissioning process has to select techniques that can guarantee and optimize the protection of workers, the public, the environment and the generation of waste. In compliance with the general regulation on nuclear facilities (both the Decree of 11 December 1963 concerning nuclear facilities and the Ministerial Order of 10 August 1984 concerning quality processes inside nuclear facilities), the decommissioning process has to be assessed and managed in the same way as the operational period of the facility in terms of safety and radiation protection. Additionally, ASN can require that the operator provide documents regarding specific safety and radiation protection decommissioning activities (for example: decommissioning of a reactor vessel, decontamination of buildings) for review by ASN and IRSN. This assessment may lead to additional constraints.

ASN requires that waste packages and unpackaged waste accepted for processing, storage and/or disposal must conform to criteria consistent with the safety case. An example of such a requirement can be found in the Decree of 4 September 1989 authorizing the creation of the Centre de l'Aube repository (article 6) and the Basic Safety Rule RFS III.2.e that addresses LILW-SL.

Another example relates to HLW and ILW-LL. In 1991, despite the absence of a site for a geological disposal and therefore, the absence of a relevant safety case, the Basic Safety Rule RFS III-2-f defined criteria for the waste, based on a multi-barrier approach. At the same time, the

specifications of the various "families" of waste to be generated by La Hague plant were reviewed and approved. The characteristics of the different HLW and ILW-LL families were taken into account by ANDRA in its studies (notably for the safety assessment) and a progressive procedure from the perspective of acceptance in the future geological disposal facility has been put in place by ANDRA.

Article R-1333-52 of the Public Heath Code requires that the sealed source no longer used be returned to the supplier. The supplier can return the source to the manufacturer or dispose of it in an authorized installation. The supplier shall have sufficient capacity to store the sources safely. The management of unsused sealed sources is described in detail in the second national report on implementation by France of its obligations under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (sections J, F.1.2.3 and F.1.2.4.). In the legal and regulatory framework there is nothing prohibiting sealed sources from being returned to the manufacturer from outside of France.

The 2006 Law on Transparency and Safety in the Nuclear Field requires that the licensee demonstrates that technical or organizational provisions are taken or foreseen during the design phase, the construction and operation and decommissioning phases (…) in order to prevent or limit hazards posed by the facility (Art.29. I). The decree of 11 December 1963 requires that the safety case describes the analysis of provisions undertaken to prevent hazards and measures that are able to limit the likelihood of an accident and its effect should it occur. Nevertheless, there are not specific regulatory requirements for the storage of radioactive waste.

At the moment, in the design and construction of a radioactive waste storage facility, ASN does not require that the licensee take into account the likely period of storage of wastes, the preferable use of passive safety features, or the potential for degradation during that period given the natural site characteristics that could impact performance such as geology, hydrology and climate. In the case of storage facilities provisions for the retrieval of the waste are included in the safety reference levels of WENRA. These requirements should be implemented in the ASN regulations by 2010. For the design and construction of new storage facilities, ASN asks the Advisory Committee to assess the application of the licensee in light of these requirements.

Clearance and Recycling

WS-R-2, 3.8, 3.17, 5.8, 5.9; SS115; RS-G-1.7

The concept of clearance is not implemented in France in terms of nuclide-specific clearance levels as specified in Agency Safety Standards [BSS 115; RS-G-1.7] and elsewhere. Material considered contaminated is treated as waste and its final disposal takes place according to the established procedures for waste, e.g. in the repository for very low level waste located in Morvilliers and operated by ANDRA. Recycling of material after clearance is thus not an issue, with rare exceptions (e.g. lead for shielding may be recycled for specified purposes within the nuclear industry).

Nevertheless, a 'nuclear waste zone' can be 'declassified' following procedures that will separate non-contaminated material from contaminated material. A nuclear waste zone may be declassified if the implementer proves that all areas or all components of the facility that previously have been considered contaminated have been cleaned and decontaminated. This distinction is primarily based on judgment of whether there is any possibility of the material being contaminated. This judgment should be supported by an analysis of the conditions of operation of the installation, and the application of a safety margin as part of a precautionary approach. The possibility to declassify a nuclear waste zone has to be confirmed by verifying that the decision criteria defined by the operator are met. The criteria must be specified and justified, and must be between the acceptable modeled residual activity and the detection limit of the measuring equipments. An impact study must be provided by the operator for each installation being decommissioned showing that the

impact of living in this area shall remain sufficiently low. The decision criteria shall not be simply derived from the value of the impact assessment. The radiological monitoring of any conventional waste leaving the installation and the site constitutes a third line of defense. If judged contaminated, the waste produced by the decontamination will enter the appropriate radioactive waste stream.

The management of conventional waste produced by nuclear installations must be specified in the "waste study" required by the order of 31 December 1999 The stream of conventional waste can be controlled by the regulator because, according to the decree on the Classification of Installation for the Protection of the Environment, installations where such conventional waste is treated must be authorized.

In the case of the release of nuclear installations from nuclear regulation after completing the decommissioning (only a few have occurred since the establishment of the guidance on the decontamination of the nuclear waste zone), a document signed by DGSNR and the local prefect states that any additional work inside the area should be preceded by radiological control in order to verify that it is safe to build and operate new facilities, including dwellings. This document will be recorded in the office which keeps records on delimitation of lands in France. It is not considered that a site can be released without any restrictions.

In conclusion, while clearance is defined [BSS 115; RS-G-1.7] "as the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control by the regulatory body", the approach taken by France is to effectively assure that material that is 'cleared' can not be considered radioactive. This means that the concept of clearance of material in the IAEA sense is not applicable. The law of 13 June 2006 confirms that ASN can enforce this practice with all future declassifications of nuclear installations. This approach is more restrictive than the approach specified in IAEA Safety Standards. At the same time, release does occur under stringent conditions. The IRRS team suggests that this should be openly communicated so that all interested parties know of the stringent measures taken to proterct the public or environment from radiological risks associated with such releases.

Discharge Control

GS-R-1 §5.25, 5.27; WS-R-2, 5.8; SS115 III.3, III.4, III.9-13

A general rule (Order of 11/26/99 a8 & a15) prohibits any uncontrolled discharge. Each BNI licensee has to define their required monitoring programme. The control systems needed to check the compliance of the discharges with the license are specified. The most important discharge limit is the annual total amount of radioactivity discharged. In some cases, this limit is defined for some categories of radionuclides. Every year the operator has to calculate the dose generated by its releases.

For installations authorized according to the Code of Health, Article R1333-12 requires that the licensee shall be authorized to discharges radioactive effluents. An order establishing criteria for radioactive effluent discharges is currently under preparation. Nevertheless, Circular DGS/DHOS n°2001-323 of 9 July 2001 applies.

Although the procedural matters associated with authorization, review and assessment are governed by different legal documents and guidelines, there is no generic regulation establishing a unified discharge limit. Limits are effectively set through licensing conditions that are site-specific, and strongly dependent on what the review of optimization and BAT yields in terms of the licensee's capability to limit discharges. Limits may be set fairly strict in relation to what can be achieved (e.g. for tritium and C-14 where discharges are in close correlation to electrical output), or less stringent where large fluctuations may be expected (e.g. Cs and Co). Nuclide-specific measurements are performed according to protocols determined by ASN.

Chronic Exposure & Remediation

GS-R-1 §5.25, 5.26, 5.28; SS115 VI; WS-R-3 2.2-7.5

The licensee has to implement exposure monitoring measures when exposure is likely to harm the health of persons. Due to the fact that most of these work places are ICPEs the responsibility of the activity is also covered by the Environment Code. In the case of radon, the obligation to implement radon exposure monitoring is incumbent upon owners or operators of places open to the public when the latter is subjected to an exposure to natural radiation likely to harm its health (Art. L1333-10 of the Public Health Code).

The person or entity responsible for a nuclear activity or for a past radiological activity is required to set up an exposure monitoring system and to clean up the site according to the procedures ordered by the Prefect. This person or entity collaborates in informing the population and implementing the protection measures decided by the Prefect. In the absence of a known or solvent person responsible, the same obligations can be imposed on the site owner (Art R1333-89 of the Public Health Code). Similar obligations exist for contaminated areas related to longer lasting activity associated with specific facilities such as ICPEs (within the Environment Code) or mining (within "Code des Minier").

In the case of sustained exposure of persons to ionizing radiation, the Prefect should implement one or more of the following measures: 1) delineation of the boundary within which measures to reduce the exposure are implemented; 2) setting-up of a system for population exposure monitoring and, if necessary, epidemiological monitoring; 3) regulation of access to or use of land and buildings located within the delimited boundary; or 4) restriction of the marketing and consumption of foodstuffs and water produced and distributed within the delimited boundary (Article R1333-90).

For NORM industries defined by the Order of 25 May 2005, the exposure to ionizing radiation of natural origin is measured following the provisions stated in the annexes of this Act. In view of the results, the ministers for Health and Employment define, by order and by category of activity, the measures to be taken for protection against ionizing radiation. Such measures cannot go beyond those imposed on nuclear activities in application of this Code of Labour. The following categories of work activities are of concern: 1) professional activities during which persons are subject to an internal or external exposure involving the elements of the natural families of uranium and thorium; 2) professional activities that include the use or storage of materials containing naturally occurring radionuclides even though the material was not used because of their radioactive properties; and 3) professional activities leading to the production of residues containing naturally occurring radionuclides. A generic action level (1 mSv/y) is only defined in the Labour Code for occupational exposure in these situations. This may be very low depending on the situation.

In the case of areas contaminated by past practices, ASN and local authorities are informed of the existence of these areas even if the exact location can not be determined. A Circular of the Ministry for the Environment of 1997 stipulates that the Prefect is responsible for the management of polluted sites. A specific guideline was issued in 2000 in order to help local authorities in the management of these situations. The levels of satisfactory decontamination, proposed by ASN, are determined on a case-by-case approach. No generic level has been yet defined.

Article R. 1333-90 of the Public Health Code requires that when a long term potential exposure has been identified, the authorities undertake one or all of following actions:

- informing the local population;
- identification of an area where specific measures are needed;
- monitoring of exposure;

- restriction of the access to the area or activities in the area;
- intervention to reduce exposure to people.

The guide DGS/DPPR of October 2000 established a methodology concerning the management of industrial sites potentially contaminated by radioactive material. This guide does not actually require a generic reference level, but recommends that the dose should not be higher than a limit established by the authorities. ASN has not established generic reference levels for intervention, nor specific reference levels. The IRRS team was informed that this should be done on a case-by-case basis. Establishing the limit for public exposure in the case of remediation actions could be very difficult and in some cases almost impossible (e.g. in the case of NORM). The establishment of guidance on a generic intervention level in advance that could be reviewed on a case by case basis will increase the public acceptance and confidence in the regulatory authority.

In application of the European directive 98/83/CE of 3 November 1998 on the control of drinking water, the authorities shall conduct assessments of the drinking water, and if necessary, will establish restrictions on drinking if the annual dose is higher than 0.1 mSv.

A general legal and regulatory framework is in place for the protection of workers, the public and the environment when remediation programmes are undertaken (Article L512-12 of the Environmental Code), but until June 2006, there were no differences between pollutions by chemical material or pollution by radioactive material. On the basis of the 2006 Law, ASN has the opportunity to develop the regulations needed for the remediation of contaminated sites with radioactive materials. The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes requires that ANDRA collect, transport and dispose of radioactive waste and remediate polluted sites contaminated by radioactive material (Art.14).

Currently, private owners should pay for ANDRA to do the cleanup or, if the owner cannot pay, the authorities can require ANDRA to conduct the cleanup anyway. ASN is involved in the application of the new legal framework to establish rules to assist in financing the costs related to the remediation of polluted sites. ASN will also be involved in the changes to the control of this kind of remediation, in conjunction with DPPR at the ministry of environment.

According to ASN, in the case of polluted sites, intervention is needed if there is a risk for the population to be exposed at non-appropriate levels, although no specific inappropriate level has yet been established. The principles of justification and optimization are taken into consideration on a case by case basis. Intervention does not mean systematic remediation, since the type of remediation required depends on the future use of the site. The principle of optimization is applied as far as reasonably practicable since one of the most important issues in that case is the lack of funds. For example, the principle of justification is applied in the case of smoke detectors and lightning rods. ASN and the stakeholders have established a plan to recover radioactive smoke detectors until 2017. One of the recommendations of the draft National Plan for the Management of Radioactive Materials and Wastes, which has to be established by decree before 1st January 2007, deals with the accelerated removal of radioactive lightning rods.

The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes requires that a report be provided in 2009 on the management of NORM waste. This report may recommend new solutions at that time (Article 4).

The legal framework provides for establishing restrictions and controls that may be placed upon the use of or access to an area before, during and, if necessary, after remediation. The circular of 16 may 1997 on the administrative procedure for polluted sites contaminated with radionuclides explains that public easement and local orders can be established on a polluted site in order to restrict access or simply allow the company in charge of the remediation to work on the site. After remediation, an easement can be established, in order to remind persons of the presence of the

contaminated site (or former contaminated site) in official documents (guide DPPR/DGS October 2000 – IV.2.2).

The guide DGS/DPPR of October 2000 established the methodology to investigate potentially contaminated areas and to designate as contaminated areas those areas requiring remediation. This methodology has been established consistently with the strategy of the Ministry of Environment for sites polluted with chemical materials. ASN has not yet established safety criteria for the remediation of contaminated areas, including required conditions at the end points of remediation. According to ASN this strategy will soon be revised in order to give more importance to the actions required to be taken in remediation activities. The circular of 16 May 1997 on the administrative procedure for polluted sites contaminated with radionuclides established the rules to proceed with the remediation of a polluted site. This circular shall be updated to define the responsibilities of ASN in this regard. The guide DGS/DPPR of October 2000 proposes criteria to facilitate the decision making process in order to approve the strategy chosen by the party responsible for the remediation. The guide SD3-D-06 of 16 July 2006 defines two main principles for the remediation of polluted sites: 1) remediation must be accomplished by workers who are allowed to work in radiation controlled areas; and 2) the management of radioactive waste must be appropriate.

The guide DGS/DPPR of October 2000 requires that decisions on remediation be taken after consultation of stakeholders, especially the people living in the area (IV.2.3.1. and IV.4).

The guide DGS/DPPR of October 2000 requires three kinds of activities for conducting safety and environmental impact assessments and setting up programmes for optimized intervention measures to address the cleanup of the affected areas and facilities: 1) a verification of non-contamination, 2) a simplified study of hazards, and 3) a detailed study of hazards. Safety and environmental impact assessment shall be conducted as well. Due to the extremely low dose criteria set down in the regulations in force for remediation activities it is unlikely that there is room for an optimization process in this activity.

The guide DGS/DPPR of October 2000 requires that the goal for remediation be established as the reference levels for remediation. The guide SD3-D-06 of 16 July 2006 requires that the management of radioactive waste be prepared taking into account ANDRA's recommendations. The circular of 16 May 1997 on the administrative procedure for a polluted site contaminated with radionuclides requires undertaking specific action if the OPRI (now IRSN) report concludes that the site needs new remediation or investigation. In that case, easement can be established to document and maintain the knowledge of the contaminated area.

Decommissioning

GS-R-1 §5.25, 5.26, 5.27; WS-R-2 6.1-6.13

Decommissioning is considered from the creation of the facility (see the 2006 Law on Transparency and Safety in the Nuclear Field, Article 29.I, and the draft decree in application of the law). Nevertheless, decommissioning is not part of the authorization for creation of the BNI. When an operator decides to shutdown a facility, ASN must be notified of the decision, and the required documents, including a safety report and general supervising and maintenance rules, must be established to obtain a specific authorization for the dismantling operations (see the 2006 law about transparency and security in the nuclear field, Article 29.V and the draft decree in application of the law, and previously the decree of 11 December 1963, modified). As long as the facility is a BNI, the operator must comply with the corresponding requirements and this is verified through inspections. The operator always remains responsible for the safety of its installation (see the 2006 Law on Transparency and Safety in the Nuclear Field, art. 28, and previously the decree of 11 December 1963). The IRRS team was informed that there is no regulation specific to decommissioning, but that ASN is already working on a draft regulation.

Disposal

GS-R-1 §5.25, 5.26, 5.27; WS-R-1 2.1-2.10

The requirements to be observed by a radioactive waste producer before acceptance of LILW-SL waste packages in a surface repository (currently the Centre de l'Aube repository) are in the Basic Safety Rule RFS III-2-e. As required by the RFS, a formal acceptance procedure has been implemented by ANDRA.

The situation concerning HLW and ILW-LL is different because unconditioned and conditioned waste were generated while studies regarding a geological formation repository were in progress and even now are not yet finalized. Consequently, there is no repository for this type of waste.

The 2006 Law about Transparency and Safety in the Nuclear Field applies to radioactive waste disposal facilities, as does the general regulation on nuclear installations.

Basic Safety Rule RFS I.2 - 19 June 1984 on Siting and Design of Near Surface Disposal of Low and Intermediate Radioactive Waste, and the RFS III.2.f - 10 June 1991 on Siting and Preliminary Design of Geological Disposal require the operator to design and operate a disposal for achieving the protection of people and the environment both short and long term.

The main radiological safety criterion for both a near surface and a geological repository is the dose received by the public. The dose is optimized to 0.25 mSv/year extended exposure associated with events which are certain or highly probable for a period of at least 10,000 years. Beyond this period of stability of the geological barrier, the same dose constraints for the public (0.25 mSv/year) is used as a reference value.

Basic Safety Rule RFS I.2 - 19 June 1984 for disposal of low & intermediate level short-lived waste establishes a list of criteria (6.5) in order to select a site and requires the operator to investigate and properly characterize the envisaged site; requires that the operator evaluate the expected releases of radioactive material over direct and indirect pathways (4.2) and requires that radiological exposure of the population be evaluated for all likely situations (4.2) including both normal and accident conditions.

Other Basic Safety Rules on potential effects of human induced external events apply to radioactive waste disposal (RFS I.1.a – 7 October 1992 on airplane crash). The effects of seismic events must also be assessed (RFS I.2 - 19 June 1984 – 4.6).

The RFS I-2 requires that studies concerning radionuclide migration by water and air for a disposal facility be conducted with conservative hypotheses and assumptions. In practice, the safety case of the Centre de l'Aube Repository is based on a deterministic method. It first considers a normal evolution scenario. Uncertainties analysis and sensitivity analysis (different values of a given parameter) are performed and provided in the safety file of the repository.

Protection criteria for occupationally exposed workers and members of the public in normal operation and accidents are defined in the specific requirements imposed on the operator in the Labour Code and the Public Health Code (§ I.6 to I.10).

The application of the interdependency principle between the operator of a surface repository and waste generators consists of specifications set out by ANDRA and acceptance procedures based on a technical and quality file provided by the waste generator and reviewed and assessed by ANDRA. This requirement is established in the RFS III.2.e and in the specific requirements imposed omn the operator in the authorization of the Centre de l'Aube repository, ANDRA (§ II.2).

Article 3.1 of RFS III.2.e (which refers to Article 13 of the Law of 30 December 1991 now incorporated in the Code of Environment), and the specific requirements imposed on ANDRA (§ II.1.2) establish the waste acceptance criteria and the operational and post-closure safety of a

surface disposal facility. There are also criteria not directly concerning the radionuclide content, most notably in the areas of chemical content, containment performance, and mechanical behaviour (including resistance in case of fall). These criteria are connected to the safety of the repository in its operational and post-closure phases.

The specific requirements imposed on ANDRA with regard to the Centre de l'Aube repository (§ I.16) and the ones with regard to the Centre de la Manche repository (§ I.16) specify that a permanent safety system should be implemented in order to prevent unauthorized people from entering the installation.

The limitation of the duration of the monitoring during the post-closure phase is one of the fundamental objectives of a surface disposal facility (RFS I-2). The RFS also specifies that the repository shall be designed so as to have an intrinsic safety based on the robustness and reliability of the two first barriers (waste packages and cells) during the operational and monitoring post-closure phase for at least 300 years.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 *§*6.15 states *"The regulatory body shall provide any necessary input to the intervention process. Such input may be advice to the government or regulatory control of intervention activities".*

(2) **BASIS:** GS-R-1 *§*6.16 states ***"****Principles and criteria for intervention actions shall be established and the regulatory body shall provide any necessary advice in this regard".*

(3) **BASIS:** WS-R-3 *§*5.6 states ***"****Before the formal termination of the remediation programme and the release from further responsibilities of the organization responsible for implementing the remedial measures, compliance with criteria shall be verified and the termination shall be subject to the approval of the regulatory body"*

(4) **BASIS:** WS-R-3 *§*5.7 states *"In the event that the approved goals have not been met, further assessment shall be performed and decisions shall be taken on whether further remedial measures or additional restrictions are required. If either the remediation fails to meet the termination criteria, or the extent or complexity of the contamination is greater than was originally determined, the implementing organization shall assess the new situation. An optimization shall be performed by the responsible organization to determine a new course of action, which may include placing reliance upon restricting access to the affected area. Any such modification to the remedial measures shall be subject to the approval of the regulatory body"*

(5) **BASIS:** GS-R-1 *§*3.14 states *"Nuclear and radiation facilities and activities will give rise to some radiation exposure. This can be safely controlled by design and operational measures. However, circumstances may arise in which intervention is needed to reduce or avert exposure or potential exposure to radiation arising from an accident or from a discontinued or inadequately controlled practice, or to radiation occurring naturally at unusually high levels. In such situations the government shall appoint organizations to be responsible for making the necessary arrangements for intervention to ensure that remedial action is taken to protect the public, workers and the environment. The intervening organization shall have the necessary resources and authority to fulfil its function".*

(6) **BASIS:** WS-R-3 *§*5.5 states *"When the organization (or organizations) responsible for*

implementing the remedial measures is specified, it shall prepare a remediation plan. A remediation plan showing that remediation can be accomplished safely shall be prepared for each contaminated area, unless otherwise required by the regulatory body. The remediation plan shall be subject to the approval of the regulatory body prior to its implementation. The approved plan shall state, as a minimum: the goal for the remediation; reference levels for remediation; the nature, scale and duration of the remedial measures to be implemented; the waste disposal or storage site, as appropriate; any post-remediation restrictions; and the monitoring and surveillance programmes and arrangements for institutional control for the remediation area."

R23 **Recommendation:** ASN should be involved at an appropriate level in the general revision of the regulation on polluted sites undertaken by the Ministry of the Environment that should provide a specific regulation on the remediation of polluted sites contaminated with radioactive materials. The new regulation should follow the recommendations of the International Standards. In this process it will be important to consider that before the formal termination of the remediation programme and the release from further responsibilities of the organization responsible for implementing the remedial measures, compliance with initial criteria shall be verified and the termination should be routinely subject to the approval of by the regulatory authorities.

(1) **BASIS:** GS-R-1 §5.25 states *"The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated".*

(2) **BASIS:** GS-R-1 §5.28 states "*In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards*".

G32 **Good Practice:** The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes now comprehensively provides the necessary legal and regulatory framework in the field of radioactive waste management (including disposal), decommissioning and remediation.. This is considered to be good practice.

(1) **BASIS:** GS-R-1, §2.5 states *"If other authorities, which may fail to meet the requirement of independence set out in item (2) of para. 2.2, are involved in the granting of authorizations, it shall be ensured that the safety requirements of the regulatory body remain in force and are not modified in the regulatory process"*

(2) **BASIS:** WS-R-1, §2.1 states *"Responsible radioactive waste management calls for the implementation of measures that will afford protection of human health and the environment in accordance with a national system of radiation protection that applies the latest internationally agreed principles and requirements for radioactive waste management and radiation protection [1, 5–8]. These principles and requirements are relevant to all activities related to near surface disposal that involve or could result in radiation exposure. Particular attention needs to be given to the assessment of the various pathways by which humans might be exposed to radiation during the operation of a repository and after its closure, and to providing assurance that protection against such exposure complies with established requirements".*

R24 **Recommendation:** ASN should coordinate with the Ministry of Environment the establishment of common approach for all disposal facilities that may dispose of radioactive waste general safety requirements and regulatory regime. In this regard the regulations should be developed or reviewed to be approved and implemented according to a schedule set up by the National Plan for the Management on Radioactive Material and Waste.

(1) **BASIS:** GS-R-1 §5.26 states *"The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations".*

(2) **BASIS:** WS-R-2 §3.5 states *"To facilitate effective and safe predisposal management of radioactive waste, the regulatory body shall ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations".*

S39 **Suggestion**: ASN should within the framework of the new waste law consider the inclusion of a radioactive waste classification scheme (or schemes) or at least the basis for it in the radioactive waste management regulation. This classification scheme should consider the National Plan on Radioactive Waste Management actually in elaboration.

(1) **BASIS:** SS 115 §2.26 states *"Except for medical exposure, the optimization of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints which:*
(a) do not exceed either the appropriate values established or agreed to by the Regulatory Authority for such a source or values which can cause the dose limits to be exceeded; and
(b) ensure, for any source (including radioactive waste management facilities) that can release radioactive substances to the environment, that the cumulative effects of each annual release from the source be restricted so that the effective dose in any year to any member of the public, including people distant from the source and people of future generations, is unlikely to exceed any relevant dose limits, taking into account cumulative releases and the exposures expected to be delivered by all other relevant sources and practices under control."

R25 **Recommendation:** The dose constraint principle is considered in the regulations for the geologic disposal. The ASN should consider extending this concept to other areas

and practices in order to communicate that the derivation of limits, and the optimization procedure, originates in a constraint that has been derived to safeguard that the dose limit of 1 mSv will not be exceeded.

(1) **BASIS:** WS-R-2 §3.6 states *"To protect human health and the environment, the regulatory body shall establish requirements and criteria pertaining to the safety of facilities, processes and operations for predisposal management of radioactive waste. These shall include requirements related to handling, transport and storage as well as known or likely requirements associated with the acceptance of waste packages for disposal."*

R26 **Recommendation:** ASN should coordinate with the Ministry of Environment the regulation of radioactive waste management to ensure the necessary consistency between the different regulations, whether they are issued by ASN or the ministry for the environment for ICPEs. It is recommended to include all activities and facilities present in the country and not only BNIs. Probably this may be organized in the framework of the National Plan for the Management of Radioactive Material and Waste.

S40 **Suggestion:** ASN should consider to issue in a short term a regulation covering the design and construction of a radioactive waste storage facility, the likely period of storage, the preferable use of passive safety features, the potential for degradation during that period and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate.

(1) **BASIS**: BSS 115 §III.3 states *"Registrants and licensees shall be responsible for ensuring that the optimization process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the Regulatory Authority, taking into account, as appropriate:*

(a) dose contributions from other sources and practices, including realistically assessed possible future sources and practices;

(b) potential changes in any condition that could affect public exposure, such as changes in the characteristics and operation of the source, changes in exposure pathways, changes in the habits or distribution of the population, modification of critical groups, or changes in environmental dispersion conditions;

(c) current good practice in the operation of similar sources or practices; and

(d) any uncertainties in the assessment of exposures, especially in potential contributions to the exposures if the source and the critical group are separated in distance or time"

G33 **Good Practice:** The way the ASN is regulating, giving quantitative guidance for discharge of short lived radionuclides and controlling the discharges of installations other than BNI.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** WS-R-3, *§*3.2 states *"A generic reference level for aiding decisions on remediation is an existing annual effective dose of 10 mSv from all sources, including the natural background radiation [6]. This will normally be assessed as the mean dose for an appropriately defined critical group. Remedial measures would often be justified below the generic reference level and national authorities may define a lower reference level for identifying areas that might need remediation".*

(2) **BASIS:** WS-R-3, *§*5.4 states *"In each specific situation, remedial measures shall be based on reference levels established as part of the decision making process".*

R27 **Recommendation:** The ASN (in coordination with the Ministry of Environment) should establish generic reference (intervention) level, or generic safety criteria for aiding decisions on remediation and allowing to the establishment of the optimum strategy for facilities other than BNIs.

(1) **BASIS:** WS-R-3, *§*4.2 states *"In formulating national strategies, it shall be taken into account that it may be necessary to involve a number of government and private organizations, and provision shall be made for liaison between them. National laws and regulations covering such matters as occupational and public radiation protection, environmental protection, transport of radioactive material, mining of ores and food standards, which may be administered by different government bodies, shall be applied to create a coherent regulatory process".*

(2) **BASIS:** GS-R-1, *§*2.6 states *"The regulatory body shall have the authority: ….(1) to develop safety principles and criteria; (2) to establish regulations and issue guidance; …."*

(3) **BASIS:** WS-R-2, *§*3.7 states *"The regulatory body shall establish safety criteria for the decommissioning of nuclear facilities (see Section 6), including conditions on the end points of decommissioning."*

S41 **Suggestion:** ASN should develop the regulations needed to support the decommissioning process from the design stage till the shutdown and decommissioning of different facilities.

(1) **BASIS:** GS-R-1, *§*1.5 states *"This publication establishes legal and governmental responsibilities which are common to a broad range of facilities and activities including the following: Activities….(5) activities in radioactive waste management (such as discharges and clearance)."*

S42 **Suggestion:** ASN should clarify the policy on clearance, and communicate to interested parties including the public that, although declassification does occur, this is done whilst applying highly restrictive approaches and guidelines to safeguard public health.

4.4.6. OCCUPATIONAL RADIATION PROTECTION

GS-R-1 § 2.4 (1)

The Labour Code in Article L231-7-1 sets out provisions relating to the protection of workers against the risks of exposure to ionizing radiation. These are defined in compliance with the general principles of radiation protection of persons laid down in article L.1333-1 of the Public

Health Code. Regulations made under Article L231-7-1 are given in Article R231-73 to 113 of the Labour Code. These provisions give general arrangements of health prevention addressed in art. L.230-1 and seq. of the Labour code.

The Labour Code regulations apply to persons exposed in both practice and intervention situations and place primary responsibility for occupational protection on the head of the establishment having the authorization to use radiation. This includes responsibility for the application of preventive measures necessary for the protection of personnel, including the supply, maintenance and monitoring of personal protective apparatus and equipment, and individual exposure measuring equipment. The regulations:

- prescribe dose limits,
- require optimization of exposures,
- define controlled and supervised areas and rules and sign-posting relating to them,
- require periodic radiation safety assessments of equipment,
- require records of sources and equipment,
- require radiation safety training,
- require the appointment and prescribe the role of a radiation safety officer,
- require maintenance of exposure records,
- define the process and persons to whom exposure records are communicated,
- define notification and investigation measures in the event of overexposure,
- require occupational health surveillance and the nature of records to be kept,
- require exposure risk assessments to be carried out,
- prescribe duties of the occupational health physician,
- require communication of personal exposure and other information to staff at least annually, and to the head of the authorized establishment and occupational health physician in the event of exposures approaching the dose limits, and
- prescribe procedures for approval of laboratories and bodies undertaking internal and external dose assessment or measurement.

The provisions of the Labour Code on occupational radiation protection are generally consistent with the requirements of the BSS (Appendix I). However, they differ in the following respects:

- Occupationally exposed persons are classified in Categories A and B depending on whether the magnitude of the likely annual doses received will exceed 6 mSv. The classification is made by the head of the authorized establishment following the opinion of an occupational health physician (R231-88). However, generally an occupational health physician would not have the training to make this judgement and it would preferably be made by the radiation safety officer, or the RSO in conjunction with an occupational health physician with specialised training.
- Category A workers are deemed to be in controlled areas (R231-81). In the BSS a controlled area is not defined by the expected dose but is one where the worker needs to follow local rules including, as appropriate, the use of protective equipment to minimise exposure.
- While the use of dose constraints is specified in emergency situations (R231-79), constraints are not required by regulation to be set by the Regulatory Body in the case of normal operations (BSS 2.26).
- There is no requirement for the formal establishment of a quality assurance system commensurate with the magnitude and likelihood of potential exposures (BSS 2.29).
- In NPPs ASN inspectors have access to personal dosimetry records. Labour Ministry inspectors have access to records in other establishments. While occupationally exposed personnel in controlled areas generally use operational dosemeters as a guide to exposures (R231-94), the passive (film) dosemeters supplied by IRSN or other approved dosimetry service providers constitute the official dosimetry records. The passive and operational dosimetry R231-94) results for individual workers are to be communicated to them (Article

R231-92 III and R231-94 II) but are not provided to the Regulatory Body nor directly to the workers as a routine, and in a timely manner (BSS I.47 (a) and (b)), thus reducing the effectiveness of the Regulatory Body's oversight of radiation protection, and the ability of individual workers and employers to monitor and control exposures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** BSS §2.26 states *"Except for medical exposure, the optimization of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints which:*

S43 **Suggestion:** Consideration should be given in guidance and codes of practice to the use of constraints, which are practice-specific.

(1) **BASIS:** BSS §2.29 states "*Quality assurance programmes shall be established that provide, as appropriate:*

i. adequate assurance that the specified requirements relating to protection and safety are satisfied; and

ii. quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

R28 **Recommendation:** The ASN should consider a requirement for authorized establishments to develop quality assurance systems.

(1) **BASIS:** BSS §I.47 states *"Employers, registrants and licensees shall:*

i provide for access by workers to information in their own exposure records;

ii provide for access to the exposure records by the supervisor of the health surveillance programme, the Regulatory Authority and the relevant employer.

R29 **Recommendation:** The ASN should introduce regulatory changes so that passive dosemeter personal dosimetry results are promptly communicated directly to monitored individuals, the ASN, and employers.

5. EMERGENCY PREPAREDNESS

The overall infrastructure requirements for emergency preparedness are given in GS-R-1, paras 6.2 to 6.6, with further detailed requirements expounded in the specific Safety Standard, GS-R-2, Preparedness and Response for a Nuclear or Radiological Emergency. This section of the IRRS report assesses the role, resources and capabilities of ASN against these safety standards.

GS-R-1 §6.2 - 6.6

5.1 THE ROLE OF THE ASN

The ASN, together with its regional bodies (DSNRs), is a central advisory body in emergency matters of radiological relevance. The objective of the actions taken by ASN is to protect workers, the public and the environment in such events. The mandate covers events at BNIs as well as installations and events outside the nuclear field, including other industries, the medical sector, orphan sources and transport. The ASN collaborates closely with the IRSN in this area and directs its advice primarily to the ministerial level and to the Prefect(s) of the affected regions. Actions prompted by the emergency situations are taken by the operators for the on-site actions, and by the Prefect(s) of the affected region(s) in the case of the off-site actions.

Operators have the responsibility for drawing up the on-site emergency plan (PUI) and to define its borders with respect to the off-site plan. The off-site emergency plan (PPI) is drawn up by the Prefect. The PUI needs the approval of ASN in order to become operative. Malicious actions are covered by a planning system referred to as PIRATOM, and there is also generic planning for other events where no specific plan can be developed, such as handling of orphan sources. For orphan sources, an agreement is made with ANDRA who will assume the responsibility of bringing the orphan sources into safe storage.

The Prefect has the responsibility for the administration of stable iodine to the population close to power plants. The ASN is responsible for, and is currently reviewing, the policy with regard to handling of stable iodine.

Post-accident planning has had a lower priority in the past but is currently being subjected to up-grading, and is also recently being included as an essential element in emergency drills.

The ASN has an emergency centre at the premises of its Paris office. It has the necessary facilities for communication with other organizations involved in the emergency network, for receiving vital information from operators as well as from IRSN, and for external communications (including a press room, if needed). It is equipped to be able provide sustained function, including in situations where the outside infrastructure is under duress.

The regional offices (DSNR) play a vital and direct role in emergency events, and will send representatives to the Prefect and operator to provide technical support and to check information.

5.2 RESOURCES AND ABILITIES

The number of ASN staff involved full-time in work on emergency preparedness is limited, but the number that is available to engage in work in an emergency situation is substantial. A large fraction of the staff carries pagers and the response time is very short.

A well structured organigram has been developed for emergency organization. Key positions are reserved for individuals occupying certain positions in the ASN, and are based on these individuals' functions in the every-day work of ASN. A weekly list is drawn up of staff members on duty, who should respond shortly after having been alerted. There is some lack of clarity in the manning and there could also be improvements in the record-keeping of training received by

function specialists. The organigram also identifies a spokesperson for ASN (a high-ranking staff member) who is responsible for all external communication matters, and in this area co-ordinates communication activities with the Prefect spokesperson and (when relevant) the operator's site and central spokespersons.

A particular issue is the dependence of ASN on IRSN in certain key areas, such as the provision of source term, dispersion modelling and dose forecasting, and the delivery of actual monitoring data in the case where a release occurs. In order to operate efficiently, this requires very rapid communication between ASN and IRSN to avoid delays in recommendations to the Prefect.

5.3 DECISION-MAKING IN EMERGENCY SITUATIONS

The emergency preparedness arrangements from organizational and other perspectives are complex and involve many players at the ministerial level, national authorities (ASN with IRSN), and regional (Prefects) and operational (individual plants where an emergency situation occurs) levels. However, there is clear allocation of responsibility for notification and decision-making. The role of ASN is an adviser to the government and competent (regional) authorities. Also, well-defined interfaces exist between operators and authorities.

The relatively large number of players and wide net of communications can, however, pose a potential source of delays and loss of information, in particular in the early phases of the emergency situation. Streamlining the emergency organization and communication routes might bring benefits.

The ASN is strongly dependent on expert assessments performed by the IRSN, which are not necessarily reassessed by ASN, but which are synthesized together with other information available to ASN before being used to issue recommendations to the Prefect.

5.4 EXERCISES

ASN (supported by IRSN) carries out emergency preparedness drills 10-15 times per year with different plants and with different scopes and scenarios. With regards to NPPs, taking into account that there is only one principal type of reactor in France, this has led to the accumulation of a substantial technical knowledge base to understand and assess the large spectrum of safety threatening situations at the plant and to provide related advice and recommendations to the national and local level authorities.

However, the drills have extensively focused on the initial events of an emergency situation, typically to the emergency situation's first 6-8 hours. Much less has been planned, tested and exercised for post-accident situations.

The role of IRSN in assessing the safety situation at and the source term from the plant, as well as analysing and predicting the release (size, length and spread and transport), is vital, as is the operation of communications between IRSN and ASN during the emergency. Increased attention may have to be put on assessing the generic implications of specific scenarios for other installations, on-site or nation-wide.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §6.3 states *"The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process. Government shall ensure that competent authorities have the necessary resources and that they make preparations and arrangements to deal with any consequences of accidents in the public domain, whether the accident occurs within or beyond national boundaries. These preparations shall*

include the actions to be taken both in and after an emergency. "

S44 **Suggestion:** ASN should continue its work towards an upgrading of post-accident planning, taking into account the specific local and national conditions, that can couple with the off-site emergency plans that are already available for a large number of sites.

(1) **BASIS:** (1) GS-R-1 §4.7 states *"In order to ensure that proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes";*

(2) **BASIS:** GS-R-2 §5.8 states *"Personnel shall be assigned to appropriate positions in all operating and response organizations in order to perform the functions necessary to meet the requirements established in Section 4.*

(3) **BASIS:** GS-R-2 §5.9 states *"Sufficient numbers of qualified personnel shall be available at all times in order that appropriate positions can be promptly staffed as necessary following the declaration and notification of a nuclear or radiological emergency".*

S45 **Suggestion:** ASN should introduce a systematic and traceable training programme for the staff allocated to key functions

(1) **BASIS:** GS-R-1 §6.6 states *"In planning for, and in the event of, emergencies, the regulatory body shall act as an adviser to the government and competent authorities in respect of nuclear safety and radiation protection".*

(2) **BASIS:** GS-R-1 §4.3 states *"If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants. Whoever may provide such advice or assistance (such as a dedicated support organization, universities or private consultants), arrangements shall be made to ensure that the consultants are effectively independent of the operator. If this is not possible, then advice or assistance may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized".*

(3) **BASIS:** GS-R-1 §4.4 states that *"the use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated".*

(4) **BASIS:** GS-R-1 §4.8 states *"in undertaking its own review and assessment of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator. Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants".*

S46 **Suggestion:** ASN should seek to facilitate and accelerate, to the extent possible, communication with the IRSN to reduce the risk that relevant information for ASN's capacity to provide advice to the prefect is delayed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S47 **Suggestion:** ASN should review its own capability to assess the situation independently of the IRSN.

(1) **BASIS:** GS-R-1 **§**6.5 states that *"The emergency arrangements shall include a clear allocation of responsibility for notification and decision making. They shall ensure an effective interface between the operator and the competent authorities and shall provide for effective means of communication. The arrangements of all parties shall be exercised on a periodic basis and shall, where appropriate, be witnessed by the regulatory body.*

G34 **Good Practice**: The number of drills per year involving BNIs is very high and considering the relative similarity of French NPPs, the level of knowledge and experience on how to act in a nuclear emergency is very high. The response time to get the emergency centre operational is very short

(1) **BASIS:** GS-R-2 **§**5.13 states; *"Plans or other arrangements shall be made for co-ordinating the national response to the range of potential nuclear and radiological emergencies. These arrangements for a co-ordinated national response shall specify the organization responsible for the development and maintenance of the arrangements; shall describe the responsibilities of the operators and other response organizations; and shall describe the co-ordination effected between these arrangements and the arrangements for response to a conventional emergency. The arrangements should include provisions that can be used to formulate in detail a response to situations such as: a serious exposure or contamination resulting from contact with a source by a member of the public; the notification of a potential transboundary release of radioactive material; the discovery of a shipment containing a dangerous source that is not under control; the notification of the potential re-entry of a satellite; public concern or rumours about a threat; and other unanticipated situations warranting a response".*

(2) **BASIS:** GS-R-2 **§**5.17 states *"The appropriate responsible authorities shall ensure that:*

(a) *emergency plans [are] prepared and approved for any practice or source which could give rise to a need for emergency intervention;*
(b) *[response organizations are] involved in the preparation of emergency plans, as appropriate;*
(c) *the content, features and extent of emergency plans take into account the results of any [threat assessment] and any lessons learned from operating experience and from [emergencies] that have occurred with sources of a similar type [(see paras 3.13–3.20)];*
(d) *emergency plans [are] periodically reviewed and updated".*

G35 **Good Practice:** An ambitious and well thought through planning for the handling of 'un-planned' events, such as the handling of orphan sources, is in place.

6. INFRASTRUCTURE FOR RADIOACTIVE WASTE MANAGEMENT

The requirements for a national infrastructure for radioactive waste management are given in GS-R-1 **§** 6.7 to 6.13. The following section of this report presents the findings of the IRRS team in this area, particularly with respect to long term management of radioactive waste.

Future steps in the management of radioactive waste will be addressed in the National Plan for the Management of Radioactive Materials and Wastes. The ASN has led the working group responsible for the development of the draft plan.

National plan

GS-R-1 § 3.4; WS-R-2 § 5.3, 5.5

The study of long term management solutions for all radioactive wastes is one of the main objectives of the National Plan for the Management of Radioactive Materials and Wastes, as required by article 6 of the 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes. Besides that, the 2006 Programme Act has defined target dates for technical solutions. ASN took the initiative to establish such a national plan when it observed a certain reluctance to do so on the side of the waste producers. ASN developed a draft plan with the participation of all stakeholders in the field. The draft plan was published on ASN's website in July 2005 for public comments. Part of the plan is already included in the new law, and the complete plan is due at the end of 2006.

Until the technical solutions are available, the wastes (essentially high level waste (HLW), long lived intermediate level waste (ILW-LL), long lived low level waste (LLW-LL)) are stored in safe conditions. Producers' strategies as well as the implementation of the strategies (safety of the installations) are supervised by the ASN.

In the field of radioactive waste management, the ASN actions are as follows:

Strategy:

In early 2006 the ASN issued a report to the Government about the research into the management of HLW and ILW-LL, and contributed to drafting the law on the sustainable management of radioactive materials and waste. Besides that, the ASN periodically reviews the overall strategy of the major waste producers (EDF, AREVA, CEA) in the field of radioactive waste management.

Each waste producer is responsible for the management of its waste. In particular it has to ensure that each of its waste management options and steps are compatible with each other and with the final disposal of the waste. The ASN pays attention to the strategy, options and steps chosen by the waste producers. In addition, the overall consistency of the radioactive waste strategy is one of the objectives of the National Plan.

International obligations:

The case of repositories has been referred to in article 37 of the Euratom Treaty. They have received favourable recommendations from the EC. The transition from operational status to post-closure status of the Centre de la Manche similarly received favourable recommendations.

In addition it is to be noted that France approved the Espoo Convention on the Evaluation of the Environmental Impact in a Transboundary Context. The Espoo Convention was approved and made applicable in France through the Act n° 200-328 of 14 April 2000 and the subsequent Decree n° 2001-1176 of 5 December 2001. Nuclear installations are submitted to the Espoo Convention according to item 3 of Appendix I of this Convention.

Waste acceptance criteria

WS-R-1 § 5.1-5.12; WS-R-2 §5.31-5.32

The responsibility to establish criteria for acceptance of radioactive waste produced by the licensee belongs to ANDRA, or to the licensee of the predisposal waste management facility, such as CENTRACO. The responsibility to verify compliance with the criteria is the same. Nevertheless, the ASN checks by inspections that the system is properly managed in the installations that produce the waste.

ANDRA is in charge of controlling the waste quality system put in place by the waste producer and reports to the ASN. In addition, ANDRA's activities in this field are controlled by the ASN through inspections.

The ASN requires that the waste packages are accepted by the repository operator (namely ANDRA for the Centre de l'Aube repository). The system put in place is mostly a quality management system. It is composed of:

- a regulatory framework: RFS I.2, RFS III-2-e, the specific requirements imposed on the operator of the Centre de l'Aube repository,
- waste acceptance specifications (set out by ANDRA) in conformity with the safety case,
- an acceptance procedure for each 'family' of LILW-SL packages to be followed by the waste producer (subject to approval by ANDRA, which reviews and assesses the technical dossier and the quality management document provided by the waste producer),
- declaration of the characteristics of each waste package to ANDRA (computerized tracking system),
- supervision of the producer by ANDRA (by means of periodical audits on sites and by means of non-destructive and destructive tests on some real waste packages),
- ANDRA's reports on its actions with regard to the waste producers (sent to the ASN),
- ASN's inspections of ANDRA's actions.

This system has been adapted to the situation of HLW and ILW-LL because a geological formation repository does not exist up to now.

The ASN is of the opinion that features adopted for waste characterization and process control provide confidence that the properties of waste packages will be ensured. Those characteristics and properties of waste packages are taken into account in the safety case each time it is updated and, as such, are reviewed by the ASN and its technical supports (IRSN and, if necessary, the Advisory Committee).

Waste classification

WS-R-2 § 3.5

Radioactive waste classification in France is based on the following two parameters:

- activity level, and
- half-life of the radionuclides contained in the waste.

Consequently there are five categories of radioactive waste:

- HLW (high level waste),
- ILW-LL (long lived intermediate level waste),
- LILW-SL (short lived low and intermediate level waste),
- LLW-LL (long lived low level waste),
- VLLW (very low level waste).

For each of these categories, the long term management solution is either in existence (VLLW and most of LILW-SL) or under study (essentially HLW, ILW-LL, LLW-LL).

National inventory

The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes requires ANDRA to establish and update, with a 3 year period, the inventory of radioactive material and waste.

The quantities in stock and anticipated in the future are provided by the National inventory of radioactive waste and recoverable material, produced by ANDRA, with the help of waste producers, under the supervision of the public authorities (among them the ASN). The National inventory also describes the various types of radioactive waste (called 'families' of radioactive waste) within each aforementioned category of waste.

The inventory was published for the first time in 2004, and updated in 2006. One part of this document contains information on polluted sites. Other inventories exist on this issue, such as the BASIAS and BASOL inventories at the Ministry for the Environment. IRSN also has an inventory of former uranium mining sites in France (the MIMAUSA inventory).

Chronic exposure and remediation

SS115 App. VI; WS-R-3 § 2.2-4.7

For the predisposal management, and especially for the storage of radioactive waste produced by the remediation of polluted sites, ANDRA has set up agreements with CEA and AREVA installations to store the waste safely. For the disposal of the waste, ANDRA either operates facilities or studies projects that should be designed in order to dispose of waste produced by remediation. In particular, the 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes requires that a disposal facility for radium bearing waste should be in operation by 2013 (Article 4).

The technical capabilities (qualified human resources) exist in France, for evaluating the impact of existing chronic exposure scenarios and making recommendations to the authorities regarding actions to be carried out. A list of societies that are qualified to conduct remediation of radioactive material has been established.

Producers of NORM waste should manage their wastes in appropriate disposal facilities. A circular of 25 July 2006 from the Ministry of the Environment requires that the impact of such disposal shall be evaluated by the operator. This evaluation may be submitted to the inspectors of the Ministry of the Environment. The Programme Act on the Sustainable Management of Radioactive Materials and Wastes (28 June 2006) requires that a report shall be produced on the management of NORM - TENORM waste by 2009.

The responsibility of the licensee using materials containing natural occurring radionuclides (NORM, not used for their radioactive, fissile or fertile properties) is introduced by Art. L1333-10 of the Public Health Code.

The strategy for the remediation of polluted sites is established by the Ministry of the Environment, which guarantees the consistency of the regulatory framework.

The ASN is not directly responsible for the safety of remediation actions that are carried out under the control of the prefect and inspectors of ICPEs (Installations Classified on Environmental Protection Grounds). Nevertheless, ASN recommends to the local authorities that the radioactive waste be managed to comply with the ANDRA acceptance criteria for low level and very low level waste. ASN inspectors can nevertheless assist the local inspectors to inspect the remediation of a polluted site.

The ASN, DPPR, the Ministry of Industry and ANDRA are discussing the framework needed to implement the provisions of the 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes. The new framework should take into account the existing system for non-radioactive polluted sites. In particular, ANDRA is given the lead responsibility in the remediation of polluted sites contaminated with radioactive materials. ADEME already has this responsibility for polluted sites contaminated with non-radioactive materials.

One of the aims of environmental surveillances is to detect radioactivity due to an accident, in France or abroad, and to aid in the decision on the need for intervention. The existing radiation levels and environmental radionuclide concentrations are regularly characterised by IRSN. Furthermore, ASN is developing a national network of environmental radioactivity measurements in order to organize monitoring of radioactivity in the environment. IRSN takes part in this network through its contribution to radiological monitoring of the entire country.

Disposal

WS-R-1; DS354

The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes set the general framework for the investigations to be made, so that ANDRA should be able to submit an application for a geological disposal facility in 2015. The details of the criteria to select the site and the safety issues to be addressed in such a case are established in the Basic Safety Rule III.2.f of 10 June 1991.

The safety case of the installation (storage facility, repository) considers normal and accident conditions, for example:

- A scenario concerning the fall of a waste package is taken into account,

Hypothetical situations corresponding to random events are taken into account in the safety case of a repository.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 § 6.7 states *"Radioactive waste generated in nuclear facilities and activities may necessitate special considerations, particularly in view of the long time-scales and different organizations which may be involved from its generation through to its final disposal and the closure of a repository. Continuity of responsibility between the organizations involved shall be ensured. Consequently, national policies and implementation strategies for the safe management of radioactive waste shall be developed, in accordance with the objectives and principles set out in the IAEA Safety Fundamentals publication on The Principles of Radioactive Waste Management [4]. These strategies shall take into account the diversity between types of radioactive waste and shall be commensurate with the radiological characteristics of the waste. The regulatory body shall ensure that an appropriate waste classification scheme is established accordingly."*

(2) **BASIS:** WS-R-2 § 1.4 states *"In the design of facilities and the planning of activities that have the potential to generate radioactive waste, measures are put in place to avoid or reduce, to the extent practicable, its generation. Waste and other residual materials are appropriately collected or segregated after collection, as necessary. They may be released from regulatory control if they do not require further consideration from the viewpoint of radiation safety. This includes the controlled discharge of effluents produced during predisposal operations. As far as reasonably practicable, the reuse and recycling of*

materials are applied as means of minimizing waste generation. The remaining waste is processed in accordance with the national strategy for radioactive waste management for storage or disposal."

G36 **Good Practice:** ASN played a very proactive role in the elaboration, discussion and approval by the Government of the 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes. At the same time ASN took the lead in the elaboration of the first draft of the National Plan for Radioactive Waste Management, which includes NORM and TENORM and which should have been presented to the Government for approval before 31 December 2006, and updated every three years for all radioactive waste streams.

(1) **BASIS:** GS-R-1; § 2.6 (13) states **"***The regulatory body shall have the authority: ... to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, Safety, and transport of dangerous goods"*

R1. **BASIS:** WS-R-3; § 4.1*"A national strategy shall be formulated to specify, prioritize and manage remediation situations and to ensure that an adequate legal and regulatory framework, supported where necessary by appropriate guidance material, is in place so that workers, the public and the environment are protected when remediation programmes are undertaken [17]. This strategy shall be commensurate with the risks associated with the contaminated areas and the approach to remediation shall be graded such that the actions to be taken can be prioritized according to the risks".*

(1) **BASIS:** WS-R-3; § 4.4 states*"It shall be ensured by means of the legal framework that adequate funding mechanisms are available and that responsibilities are assigned for the financing of remedial measures and protective actions to be taken after remediation that are proportionate, manageable and economically sustainable. It shall be ensured by means of the legal framework that provision is made for adequate funding to be available if organizations or individuals are unable to meet their liabilities. In order to help ensure that the remediation is adequately funded, the regulatory body shall identify all those persons or organizations responsible for the contamination and other appropriate persons to finance the remediation. Voluntary co-operation between owners, industry and the community in partnership shall generally be encouraged in preference to regulatory action."*

G37 **Good Practice:** ASN has contributed to determining whether any intervention is needed for reasons of radiation protection, bearing in mind that the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention. A lot of work has been done to identify situations requiring remediation actions.

S48 **Suggestion:** ASN should continue its efforts to coordinate with the Ministry of the Environment to establish a common regulatory regime for the remediation of areas contaminated with radioactive materials including the safety of remediation actions that are carried out under the control of the prefect and inspectors of ICPEs (Installations Classified on Environmental Protection Grounds). ASN should also be involved in changes related to control of this kind of remediation, in cooperation with DPPR at the Ministry of the Environment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 § 4.3 states *"If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants. Whoever may provide such advice or assistance (such as a dedicated support organization, universities or private consultants), arrangements shall be made to ensure that the consultants are effectively independent of the operator. If this is not possible, then advice or assistance may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized."*

(2) **BASIS:** WS-R-3 § 4.2 states *"In formulating national strategies, it shall be taken into account that it may be necessary to involve a number of government and private organizations, and provision shall be made for liaison between them…."*

G38 **Good Practice:** The establishment by ASN of a list of organizations qualified to evaluate the impact of existing chronic exposure scenarios and to make recommendations to the authorities regarding actions to be carried out is considered a good practice.

7 MANAGEMENT SYSTEM FOR THE REGULATORY BODY

Introduction

The requirement for a regulatory body to have a quality management system for its regulatory responsibilities and functions is given in GS-R-1, §4.5. The extension of this approach to operators and service providers, as well as the regulatory body, is covered in the specific Safety Standard, GS-R-3, the Management System for Facilities and Activities, where further detailed requirements are given.

GS-R-1 §4.5

A documented management system (MS) is a coherent system setting up the way in which the organization is led and managed from its mission and vision. It describes the values, principles, policies, goals, structures and processes, roles and responsibilities, human and other resources, and renewal of the organization, all of which guide the management behaviour of the organization. An integrated MS provides a single framework integrating safety, health, environmental, quality and economic elements. It covers and documents all the elements of the MS in a coherent, easy-to-understand way available to all the staff members.

Many key elements of the ASN MS have been developed and implemented individually in ASN throughout its years of functioning. However, the development of a more integrated, organized and formalized MS has only recently started and was, at the time of the review, in its early phase. Therefore, the review against GS-R-3, The Management System for Facilities and Activities, has been at a high-level only. However, areas of security, physical protection and nuclear material accounting and control, which often are an integral part of the MS (GS-R-3, §2.1), do not currently fall under the responsibility of ASN and were therefore excluded from the MS review scope.

The review covered three main dimensions of the ASN MS:

- ASN's in-house management system, i.e. the management system applied at ASN,
- ASN's MS oversight of licensees' MS (e.g. safety culture),
- ASN's MS interface with and oversight of its TSO (IRSN) and its, as well as licensees', contractors and sub-contractors. This dimension considers how ASN ensures that the TSO, the licensee and the supply chain have an effective MS (including such aspects as safety culture); monitors the system and its performance (ensuring open channels to know what's going on in the operating organizations); and takes actions as needed.

At the outset it should be noted that GS-R-3 has not formally been applied and enforced in France (in ASN or to its licensees and contractors). Therefore, for example, there are no requirements and procedures in place related to safety culture.

Also, during the IRRS mission, ASN was reorganized and a new five member Commission established. From a MS viewpoint, this represents two current challenges to ASN – namely, the successful organizational change and the introduction and implementation of a cultural change. Therefore, it was considered too early to assess to what extent the new Commission and new senior management of ASN have the intention and commitment to continue establishing, implementing, assessing and continually improving ASN's MS (GS-R-3: §3.1, §3.4, §3.7, §3.12).

ASN has been developing its MS more systematically since 2003, but already before that time several MS elements had been introduced and implemented. As of the time of the mission, ASN has introduced several MS components described in the GS-R-3 and, in general, many more MS elements in practical use are formalized and documented according to the requirements of GS-R-3.

Well developed elements of the ASN management system

These include the following:

- ASN's main processes are:

- management processes: organization, governance, relations, quality management;
- business processes: regulation, authorization, control and supervision, information and communication, emergency preparedness;
- support processes: human resources, other resources, information management:

For each process, detailed notes, procedures, internal guides and implementation policy notes describe and give practical guidance on how ASN currently operates. Documentation of the processes follows a graded approach in which most effort, details and resources are devoted to issues with significant safety implications, such as inspections, event analysis and emergency preparedness. ASN is developing and implementing an internal IT-system, which provides access to MS documentation at all levels for all staff members. However, managing interactions between the processes will require further development. (GS-R-3: §5.1, § 2.1, §2.8, §3.7)

- The new ASN strategy, goals and objectives, as described in a coherent manner in the published "Plan Strategique 2005 - 2007". (GS-R-3: §2.1, §2.8)
- The annual planning system: Based on mid-term plan, each ASN entity prepares an annual action plan for the next year. At the end of the year, each ASN entity reports to the senior management on the implementation of the annual plan and the results obtained. ASN also has an elaborate and stringent planning system in place with its TSO. (GS-R-3: §3.8 -§3.11)
- Clearly defined values: ASN's established and documented values are stringency, competence, independence and transparency. (GS-R-3: §3.2)
- The decision making process: The decision making process is clearly documented at the highest level of the ASN document hierarchy, namely in Reglement interieur de l'ASN; Delegation de signature.
- Quality certifications: Some regional offices have ISO 9000 certified components in their MS (GS-R-3: §5.1, §1.4)
- Human capital development: ASN has a formalized, detailed and well functioning training programme. Major resources have been allocated for the programme. During the first year, technical staff newcomers receive 60 days of training followed by 10 days per year (on average) of training later on. A dedicated group is responsible for organizing and developing the training programme. However, some important elements, such as implications of staff turnover and job qualifications, require more senior management attention and are dealt with later in this report. (GS-R-3: §4.3 and §4.4)
- Measurement, assessment, internal auditing system, organizational arrangements (units) for independent in-house MS evaluations and self-assessments: ASN has several performance indicators in place which, under the Finance Bills Organic Act, are also used by the Parliament to evaluate the effectiveness of the ASN. Examples of the indicators include number of inspections, issued authorizations, event analysis, delays in issuing authorizations and public polls. The internal audit system is well established. Every three years, each ASN entity (except the Secretariat General responsible for human resources, public communication and finances) is cross-audited by a team of fellow ASN staff members using established procedures and guiding checklists. The main purpose of audits is to review the compliance with their goals rather than to seek improvements. An independent organizational unit inside the Mission Organisation et affaires juridiques (JMO-office) of ASN has the responsibility for the audit programmes and their implementation. Self-assessment was used for the first time for this IRRS mission, and ASN has decided to upgrade the self-assessment process and integrate it into the internal audits procedures from the beginning of 2007. (GS-R-3: §6.1 - §6.16)

- Improvement: Even though not formalized, ASN has been de facto monitoring and measuring its effectiveness and results against planned and intended results (via internal audits, intensive sets of senior management meetings with departments and staff, annual planning, etc.). ASN's intention is to expand this compliance-driven approach to include also identification of opportunities for improvement. ASN has prepared an improvement procedure, which is currently in the stage of implementation. (GS-R-3: §6.17 and §6.18)
- Managing public relations: With high levels of public information and involvement, public (and media) relations are priority managed by highest ASN management both in normal as well as in emergency situations. (GS-R-3: §5.26 and §5.27)

Less developed elements of the ASN management system
These include the following:

- Policy and documented (and demonstrated) senior management commitment to establish, implement, assess and improve the MS. (GS-R-3: §3.1, §3.4, §3.7, §3.12)
- Developing and documenting regulations, in particular on the authorization and oversight of contractors[5] in the full supply chain and the process of oversight of the MS of licensees and contractors relevant to safety: Privatization, deregulation of energy markets, globalization of nuclear industry and its supply chain, increasing use of contractors, economic re-thinking and increasing efficiency requirements as well as emerging new technologies related to major upgrades of existing nuclear plants and new builds require particular attention from the new Commission and ASN senior management in developing and documenting regulations, authorization and oversight of multinational licensees and contractors in the full supply chain to ensure safety.

  In the particular case of ASN's TSO, IRSN, there is an elaborated interface system in place for planning, ordering, implementing and following-up the work assignments which IRSN is to carry out for ASN. However, from the MS viewpoint since ASN is IRSN's main single customer, ASN might benefit from establishing policies regarding the following customer management areas: (1) management of conflict-of-interest, (2) ASN's oversight principles with respect to IRSN, (3) management of intellectual property rights and protection of those rights, (4) level of details and transparency in the financial accounting of the work for ASN, and (5) establishing a vision of how ASN intends to develop its relationship with IRSN as TSO.
- Safety culture: ASN senior management's attention is warranted on the oversight of the MS and safety culture issues of the licensees and those contractors (including IRSN) that have supply roles with safety significance. It appears that currently there are no requirements for or oversight of safety culture in place. (GS-R-3: §2.5 and §2.2)
- Integrating the elements of the MS of the regional offices into the ASN MS. (GS-R-3: §2.1 and §2.3)
- Harmonizing staff engagement in different parts of the MS: ASN has a strong and long tradition of a variety of ways in which senior management meets with the staff. These meetings cover a wide variety of de facto MS issues. Staff engagement is of uttermost importance to ASN, since competence is one of the ASN values. ASN's effectiveness and efficiency might benefit from further promoting and systemizing staff engagement. This could involve areas such as annual planning, delegation and personal responsibility at work and in decision making processes, self-assessment and initiatives for improvements and raising safety concerns. (GS-R-3: §3.4)

[5] In addition to service and maintenance organizations, 'contractors' include also inspection and testing organizations and nuclear equipment manufacturers.

- Human capital development: About 50% of the staff are civil servants resulting in a high staff turnover in comparison with regulatory bodies in many other countries. Taking also into account that about 25% of ASN staff is seconded by IRSN, this raises concerns related to the long term competence and the effectiveness and efficiency of ASN's competence building efforts – in particular since competence is one of ASN's core values. Therefore, particular attention is warranted to ensure long term competence, to reconsider the rotation practice and to ensure that all individual competence requirements (qualifications, education, experience) for each position in the organization including those at the highest management level are considered in a graded manner (relevance to safety), and these competence requirements are documented and followed. (GS-R-3: §4.3 and §4.4)
- Documenting and formalizing development and management of processes: ASN's work here is beginning. (GS-R-3: §5.1 - §5.10, §5.12, §5.14, §5.17, §5.18, §5.21 - 22, §5.23 - 25)
- Completion and implementation of the procedure for dealing with non-compliances: ASN's work to begin. (GS-R-3: §6.12 - §6.15)
- MS reviews: this will be applicable in a later phase when the ASN MS is more developed and further implemented. (GS-R-3:§2.4, §6.7)

Finally, these MS elements should be integrated into a single and coherent system. (GS-R-3:§2.1-§2.3)

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-3 §3.1 states *"Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities".*

(2) **BASIS:** GS-R-3 §3.4 states *"Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system".*

(3) **BASIS:** GS-R-3 §3.7 states *"Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization".*

(4) **BASIS:** GS-R-3 §3.12 states *"Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved".*

R33 **Recommendation:** In light of ASN reorganization and management responsibility, the new Commission and ASN senior management should establish and document a policy and demonstrate commitment to establish, implement, assess and improve ASN's management system.

(1) **BASIS:** GS-R-3 §2.1 states *"A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:*

- *Bringing together in a coherent manner all the requirements for managing the organization;*
- *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;*

Ensuring that health, environmental, security, quality and economic requirements are not

considered separately from safety requirements, to help preclude their possible negative impact on safety.
—The complexities of processes and their interactions."

(2) **BASIS:** GS-R-3 §2.10 states *"The documentation of the management system shall reflect:*
—The characteristics of the organization and its activities;
—The complexities of processes and their interactions."

R34 **Recommendation:** The development of the ASN MS should be continued. As one of the next steps, a master plan with major milestones, time schedules and resource allocations should be prepared and implemented to guide the systematic development of its MS. The plan should address, inter alia, issues discussed above and the three main dimensions of the management system,

a. ASN's management system applied in-house,
b. ASN's oversight of licensees' management systems, and
c. ASN's oversight of TSO's and contractors' management systems.

(1) **BASIS:** GS-R-3 §4.3 states *"Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained."*

BASIS: GS-R-3 §4.4 states *"Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives".*

R35 **Recommendation:** In light of high staff turn over, including at management positions, regulatory needs related to the potential future developments in the use of nuclear energy, and competence as one of its core values,

- ASN should reconsider its human resource strategy in order to ensure ASN's long term competence and the effectiveness and efficiency of the competence building efforts;
- ASN should ensure that the individual competence requirements (qualifications, education, experience) for each position in the organization are considered in a graded manner (relevance to safety), and that requirements are documented and followed.

(4) - **BASIS:** GS-R-3 §1.1 states *"This Safety Requirements publication defines the requirements for establishing, implementing, assessing and continually improving a management system. A management system designed to fulfil these requirements integrates safety, health, environmental, security1, quality2 and economic3 elements. Safety is the fundamental principle upon which the management system is based. These requirements must be met to ensure the protection of people and the environment and they are governed by the objectives, concepts and principles of the IAEA Safety Fundamentals publication [1]."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
(2) **BASIS:** GS-R-3 §1.6 states *"The requirements established in this publication may be used by organizations in the following ways:* - *As the basis for the management systems of organizations directly responsible for operating facilities and activities and providing services, as described in para. 1.8;* - *As the basis for the regulation of these facilities and activities by the regulatory body;* - *As the basis for the management systems of the relevant regulatory bodies;* *By the operator, to specify to a supplier, via contractual documentation, any specific requirements of this Safety Requirements publication that must be included in the supplier's management system for the supply and delivery of products."*
S49 **Suggestion:** In light of ASN's efforts to ensure greater consistency with IAEA safety standards, the requirements of GS-R-3, e.g. those related to safety culture, should be formalized, applied and enforced by ASN.

8. POLICY ISSUES

8.1.Independence of the regulator

Background:

The effective independence of the regulatory body continues to represent a significant challenge for many Member States. Some States may encounter difficulties in separating the regulatory control from the promotion and operation of facilities or activities for a number of reasons in spite of the safety considerations. What is important is that regulators have to be able to work without pressure from promoters of nuclear energy, radiation technology and associated practices.

There are a number of key elements needed to deliver effective and sustainable nuclear and radiation safety regulatory systems so that Governments can be assured that nuclear energy and associated technologies can be used safely, that society can have confidence and trust in the regulator and that the nuclear industry can be assured that it is being regulated competently and fairly. The effective independence of regulatory bodies needs to be both de facto and de jure. Guidance on independence was adequately set out in the IAEA Safety Standard GS-G-1.1 on organization and staffing of the regulatory body for nuclear facilities.

The following elements were discussed in the context of the French legal and regulatory framework:

- The new legislation that establishes an effectively independent regulatory body
- Access to independent resources and technical advice
- Funding independence
- Balance between the operators' and the regulator's responsibilities
- Competence for decision making processes
- Leadership and management of safety.

Discussion:

The new 2006 TSN Act creates ASN as a de jure independent regulatory body. ASN has adequate capabilities as well as the right to take regulatory decisions directly to the licensee. France, Japan and others States, unlike the United States and Finland, for example, have relatively small regulatory bodies, supported by TSOs, but which make regulatory decisions by themselves as 'intelligent ustomers'. The relationship between regulatory bodies and TSOs is a key point. If the TSO works for more than just the regulatory body, arrangements should be made to ensure that the TSO has no right to work for licensees – this would be the case, for example, in Belgium according to the law of 1994.

The situation of IRSN as TSO for ASN is unique in that it has two functions: TSO for, inter alia, ASN and a research organization for other bodies. IRSN also provides services to other Ministries and bodies. In Japan JNES is the TSO for NISA, but research activities are performed by another organization. IRSN has well recognized nuclear and radiation safety research activities, but ASN does not monitor or control the IRSN safety related research programme. To avoid the potential conflict of IRSN providing technical support to both ASN and the industry, ASN has a charter (memorandum of understanding) signed in 2000 which represents a code of conduct governing the relationship between the two organizations and how technical assessments are made and under which conditions IRSN is given these tasks, how IRSN should report and what ASN does with the advice. In addition, there is an annual programme of work to be performed by IRSN for ASN. Four hundred IRSN persons are working for ASN and 50 ASN staff are seconded from IRSN to ASN where they spend an average of three to five years. Seconded staff very often return to IRSN, having obtained a

better knowledge of what ASN is doing. It was recognized that some elements, such as reporting lines agreed for particular requests, funding independence and avoiding conflict with promotional activities, can be incorporated in MOUs between regulatory bodies and TSOs.

8.2. Enhancing regulatory effectiveness and competence

Background:

Governments should ensure that the regulatory body is competent and has the necessary resources to fulfil its mission in relation to independent oversight and assurance to ensure public and environmental protection. The industry generally recognized that nuclear and radiation safety is a prerequisite for sustainable development and that effective nuclear and radiation safety regulatory control is needed.

Challenges in maintaining and enhancing regulatory effectiveness and competence remain in many Member States. There is still no consensus on how to measure regulatory effectiveness. Regulatory bodies should consider what the IAEA services can do to strengthen their effectiveness.

There are a number of factors to take into account regarding effectiveness and competence:

- Harmonization with international practices
- Commitment to resource planning
- Commitment to knowledge management
- Assessment of workforce competencies
- Commitment to staff training and development
- Commitment to continuous improvement and safety management systems
- Promotion of the sharing of experience and lessons learned
- Use of regulatory performance indicators.

A major challenge facing many Member States continues to be establishing, maintaining and improving technical competence in the regulatory body and technical support organizations as experienced staff retire, facilities age and the use of nuclear applications expands. Regulatory effectiveness and efficiency can be enhanced through:

- Merging regulatory responsibilities, previously separated amongst different agencies, into one regulatory body
- More risk-informed approaches to enhance proportionality of regulatory activities
- Regulatory body application of modern management systems
- Integrated safety oversight programmes including the use of regulatory indicators.

Discussion:

Two thirds of ASN staff are engineers and ASN has a good training programme for newly recruited personnel as well as experienced inspectors. ASN is building up a modern management system and has regular management staff meetings to exchange information and experience.

ASN does not use risk-informed regulations and PSA to the same extent as some others regulators, but this is complemented by other aspects including a deterministic approach.

8.3. Openness, transparency and stakeholder involvement (including public communications)

Background:

Openness and transparency in regulation is essential to encourage continuous improvement of performance and building public confidence. The international community promotes openness through several services. However, finding a proper balance between public availability of information and protection of confidential data remains a challenge.

Key elements are:

- Strategies for engagement of stakeholders
- Stakeholder involvement in regulatory decision making
- The basis for regulatory decisions made available to stakeholders
- Use of electronic communication, including the internet, for communication to stakeholders
- Low threshold for informing stakeholders of nuclear and radiation safety related information

Stakeholder engagement is important for effective regulation. Hence it is important for regulatory bodies to develop and implement strategies for engagement with their stakeholders so that trust in the regulatory body's competence, integrity and impartiality can be established. This was regarded as being important because, even though some stakeholders may not always agree with a decision, if there is trust and respect they will accept the integrity of the decision making process.

Discussion:

ASN has an active policy of communicating with the public as a result of a 1981 government change to improve communication with the public in all fields. This decision was made by the Prime Minister and is reinforced with the new 2006 TSN Act. Local committees near nuclear facilities did not want information in the past, but now the situation has changed. Other States like Japan and UK are also promoting information to the public and other stakeholders to ensure that they have trust and confidence in the regulatory framework.

A decision by ASN to have an information center at the entrance to their headquarters office and a publicly available website gives an insight into the importance they attach to this issue.

8.4. Leadership and management for safety

Background:

Leadership in nuclear and radiation safety matters has to be demonstrated on the highest levels in an organization. The importance of human and organizational aspects of safety and safety culture is widely accepted. An effective management system is considered essential to support leadership in order to maintain and continuously enhance a good safety culture. Assessment tools for safety culture are being developed. Advanced decision-making techniques are increasingly needed to apply resources where they will do the most good; e.g. recent events have led to concern over complacency in some operating organizations and a lack of regulatory effectiveness in identifying and proactively responding to early symptoms of emerging problems.

Additionally, it was recognized that safety management programmes are essential in assuring nuclear safety regulation throughout the life cycle of the nuclear installations and radiological practices. The necessity is well recognized of incorporating the regulatory review of the management of safety into the regulatory practices.

Key elements are:

- Safety policy clearly defined by the operators
- Safety management system

- Integration of the elements of the safety management system (safety culture, environmental, quality, financial, etc.)
- Internal assessment of safety culture
- Open dialogue between regulatory body and senior industry executives
- Internal decision-making appeal process
- Value and ethics programmes
- Self assessment by operators and regulators
- Regulatory experience included in appointing senior executives.

The recurrence of events in nuclear installations or practices may indicate a weakness in regulatory effectiveness. This could indicate that neither the operators nor the regulators have been effective in identifying and proactively responding to early symptoms of emerging problems and assuring that there is feedback of operating experience within both organizations. Political and economic changes can lead to increased tension between safety and production considerations. Both operators and regulators are recognizing the need to apply decision making techniques that focus resources to deliver safe and efficient operations. In order to meet these challenges, it is necessary to define and use new decision-making tools which integrate deterministic and probabilistic insights. Such tools offer great promises in both the design and operation of plants and in regulation.

Discussion:

Many see leadership and management of safety as an area difficult to regulate. Management of safety can be achieved but it is unclear how to manage safety culture. ASN has dialogues with EDF on many levels, and in fact this is done at the facility level, as ASN does not have resident inspectors. However ASN staff are often in the facilities for inspections or technical meetings, with resulting good knowledge of the facility and well established relations. The inspectors sometimes alert ASN headquarters to problems in the organization of operators. For example, there was a concern regarding management, leadership and culture at Dampierre NPP in 2001. As a result, ASN decided to focus on this issue and the President of ASN went to the NPP and had a general meeting with all the operators informing them that if the situation continued without improvement within one year, he would shut down the NPP.

8.5. Use of insights from operating experience feedback (OEF) into the regulatory process

Background:

Nuclear power plant (NPP) operational safety performance, in general, has remained at a high level throughout the world. Radiation doses to workers and members of the public due to NPP operation are well below regulatory limits. However we still see recurring events in nuclear installations. Enhanced operational feedback systems are needed to support the sharing of actions taken by operators and regulators towards risk reduction.

Key elements are:

- Collecting OEF;
- Analysing OEF and identification of root causes;
- Make appropriate changes based on OEF;
- Disseminating results of OEF, nationally and internationally;
- Maintaining a safety culture that promotes consideration of low level events.

Discussion

It was made clear in the discussions that OEF in radiation protection practices is rather weak at ASN as the integration of radiation protection activities into the ASN regulatory framework happened only in 2002. Nearly all OEF in radiation protection is with IRSN and there is no clear policy at ASN on how to deal with this issue. It was concluded that this is an issue in which IRRS's help, in terms of recommendations and suggestions, is needed to improve this situation.

However, OEF in NPPs is well established. EDF has a major events database, called SAPHIR, which includes all events and related analyses that have occurred, including those reported to ASN. Both IRSN and ASN have access to this database. For long term feedback, every three or four years a global review by an advisory committee, composed of representatives of IRSN, ASN, EDF and other organizations, is performed. This review covers all reported events that occurred during the review period. A strong link exists between PSR and OEF in France, because of the similarity of NPP design and the single licensee organization.

Regarding the issue of how safety culture is affected by financial constraints and how ASN oversight/supervision is exercised, it was found that financial issues are not easily dealt with in the French culture. However, more and more financial documentation and cost benefit studies have been required in order to know how much such large related programmes cost. The new ASN management system may include the integration with safety culture.

EDF has a strong and structured informal inspection programme. There are two levels of internal EDF inspectorates. The first one is for all plants under the Directorate for Nuclear Production (DPN), and covers more management and financial issues. The second internal inspectorate is under EDF's Presidency, and it performs very detailed and strict technical inspections. The latter are performed for each plant every three years and result in an action plan for improvement. These reports assist ASN to compare with their own inspection findings in order to get better insights.

ASN inspectors are trained for NPP events assessment. There are 3-4 people within SD2 who review all NPP events that have been declared over the 58 plants in France, and this is fed into the annual event programme. When an event occurs ASN asks whether such event could happen at any of the other 57 NPPs.

Dissemination of the OEF at international level is done through CEA.

8.6. Long term operation and ageing nuclear facilities

Background:

Eighty percent of the reactors operating worldwide could be eligible for a long term operation (operating life extension). Member States have demonstrated a common interest in extending NPP operating life and are at different stages in the process while varying in their national practices. Long term operation of NPPs includes various Member States' practices such as plant license renewal, life extension, continued operation and life management. Long term operation is economically attractive to plant owners while it adds value to Member States' national interests in energy security, environmental quality and economic growth. The long term operation of NPPs is one unique nuclear safety issue to be addressed by the international nuclear community.

Key elements are:

- Regulatory approach;
- Existing process for renewing / extending / re-licensing beyond the original operating term;
- Regulatory requirements and guidance;
- Regulatory inspection and monitoring processes;

- Additional regulatory strategies to reduce the collective doses arising from long term periodic inspections and extensive maintenance activities.

Discussion:

There is a major programme in EDF and ASN on the ageing of NPPs, with two major topics: one for ageing of reactor pressure vessels for all the 58 reactors, and the second for steam generators. The programme is piloted by EDF, while ASN ensures regulatory control. Rapid change in technology makes some equipment obsolete and therefore can not be replaced; therefore a new design has to be made.

8.7. New build and new technologies

Background:

This reflects a concern on whether the current approach would also be successful where foreign owned licensees might be interested in nuclear power generation, and the potential suppliers of facilities are international companies. It has already been experienced that the authorization of foreign designed nuclear power plants took a very long time and consumed a lot of resources. The logical order of decisions needed from different authorities involved ensuring the consistency of all regulatory requirements is a challenge

Key elements are:

- Current arrangements for the authorization can be used also to address the current challenges (privatized utilities, use of contractors, international nuclear industry);
- The mechanisms identified for ensuring safety of the new build plants;
- The establishment of a regulatory contact forum with the aim of producing a joint plan for an integrated licensing process;
- Stepwise licensing of new NPP projects;
- Co-operation with regulatory bodies that have reviewed and possibly licensed the NPP designs proposed to be built.

Discussion:

There is no clear policy on this issue at ASN. It is expected that the five newly appointed commissioners of ASN will develop relevant policies and strategies. The last licence granted to a NPP in France was more than ten years ago. Due to the absence of the above mentioned policy, significant problems with the supervision of the EPR were encountered. In this respect it is worth noting that a letter prepared by ASN related to this issue had to wait, for political reasons, four years before its signature and submission. With the new TSN 2006 law such situations will not occur, due to the effective independence of ASN.

For the new build in France, no change is expected to happen in the licensing process and no formal pre-licensing will be done in accordance with the existing policy. ASN has discussions with others stakeholders involved in the new built. Knowledge management in this area is also very important – ASN worked with IRSN, Siemens and Framatome on the EPR project. Through this process knowledge was gathered on how procedures should work.

Another issue with the new build is globalization: how to deal with all steps and components of a chain that is getting more globalized and how to make sure that the nuclear specific requirements, and the quality in this chain is clear at all levels. Today, the international context is an important aspect to be considered in the licensing process. It is very important that those, for example, making components understand the requirements; otherwise it will be very difficult to regulate a plant. For example, a licensee might be domestic but fully dependent on other elements of the

chain produced abroad. Nuclear specific requirements and safety culture are some of the main challenges. Questions that arise are: How can it be verified that all requirements are met? How does the regulator ensure that the licence holder puts every necessary document in the hands of regulators?

8.8. Regulatory approach – risk-informed and deterministic; or performance-based (functional-based) and prescriptive.

Background:

In some Member States, there is a trend towards risk-informed and performance-based approaches to regulation, rather than a wholly compliance-based approach (deterministic and prescriptive). Similarly, new licensing procedures are being developed to improve predictability of the process and help to reduce financial risks of nuclear power plant construction. It is therefore essential that there be a framework to guide the regulatory transition.

Key elements are:

- Expectations for balancing risk-informed and deterministic decision making;
- Guidance exists for risk-informed regulatory decision making;
- Processes for determining the safety significance of regulatory actions;
- Defined outcomes based on promoting safety;
- Prioritising regulatory activities based on safety significance.

Discussion:

Characteristics of PSAs and the basic concept of risk-informed regulation were summarized as follows:

- PSA is a method, not necessarily exhaustive, to integrate expert judgments in various fields of nuclear safety. Hence PSA results are also expert judgments based on a comprehensive methodology that integrates judgments from many different areas.
- Since PSA results are expert-based judgments and engineering judgments, it is not appropriate to utilize only PSA results in formal regulatory processes such as licensing.
- On the other hand, we see deterministic safety assessment in many regulatory rules. The analysis methods, assumptions to be taken, criteria, etc. are strictly defined and, as with other rules, compliance is required.
- Sometimes it is said that PSA and deterministic safety assessment are complementary with each other. All regulatory rules are developed based on expert judgments. Since PSA is based on expert judgment, PSA results may be used as a basis to develop or modify regulatory rules, including some deterministic safety assessments.
- PSA results include uncertainties that may be relatively small in some parts of the PSA results but the uncertainties are large in other parts such as source term evaluation, human factor analysis and seismic risk analysis.
- In utilizing PSA results in regulation, the strengths and weaknesses of PSAs must be recognized.

It was clarified that ASN's policy is the intent to use risk-informed approach to enhance its proportional and graded approach. The internal authorization process is linked to this approach when providing a formal authorization. ASN is more deterministic than probabilistic oriented and uses risk-informed analysis to help it to be more balanced in its regulations.

8.9. Participation in legal and non-legal binding international instruments and globalization of the nuclear community.

Background:

The world today is increasingly complex and the globalization of technology, business and communication, and also terrorism, affects all human activities. Therefore, solutions for increased nuclear safety and security require a multilateral approach that takes into consideration interests of key stakeholders, national policies and global trends. The Global Nuclear Safety Regime here is defined as the institutional, legal and technical framework for ensuring the safety of nuclear installations throughout the world. The objective of this regime is to reach a condition where all nuclear installations operate safely.

Key elements are:

- Multilateral exchanges;
- Bilateral or multilateral agreements;
- Participation in Conventions;
- Commitment to Codes of Conduct;
- Participation in international safety review services;
- Demonstrated openness to improvement and mutual learning.

Discussion:

The involvement as much as possible in international activities regarding nuclear safety is increasingly important to all Member States. The Convention on Nuclear Safety and the Joint Convention are examples of such involvements. However, from the French point of view, in order to ensure nuclear safety around the world, these conventions are necessary but not sufficient. An ASN aim is to cooperate as much as possible throughout the world in order to operate nuclear installations as safely as possible, learning from the good practices of others and learning from bad practices in order to reduce the likelihood of such events. These activities should be widespread among all regulators. WENRA and INRA are the appropriate forums for ASN to go further than just a national responsibility, in which ASN can try to share a global worldwide responsibility. Involvement in international issues takes significant money and time; important issues are dealt with, including technical issues. ASN gives strong emphasis to legally-binding instruments. ASN participation in international safety review services, for example IRRS, helps to improve the nuclear safety worldwide, not only in France. In the UK, for example, the participation of the operators in international reviews of IAEA or WANO are very useful and have helped in continuous improvement of nuclear installations in the UK and in the rest of the world. However ASN does not receive any feedback from WANO, only from EDF.

Openness is the key element to interactions in the international community, where it is important to show responses not only at a national level. International involvement is part of the normal ASN activities and the ASN President devotes 25% of his working time to such activities. As an example, during a real emergency the ASN President becomes the spokesman for ASN rather than the head of the technical team. In this role he communicates to the public and media on the international level.

Any nuclear accident is by definition an international event and not only a national event. A responsibility of the regulators is the promotion of the nuclear safety around the world. Different countries respond in different ways when events or incidents happen. The regulators have to work internationally to harmonize such decisions and to make additional contributions. Today, nuclear

and radiation safety issues have international considerations. Different working groups within the European Community are tackling differences in approach and are trying to reduce them.

Public protection beyond the French borders is relevant. In France, the emergency drills produce an excellent knowledge base to protect the public, based on information and analysis from IRSN based on the accident source information. ASN is committed to continuing to arrange the necessary bilateral agreements to help ensure the public is protected in the event of accidents.

8.10. Harmonization of the nuclear safety and radiation protection regulations and practices

Background:

Where separate regulatory bodies were regulating nuclear safety and radiation protection in the past, integration may become an issue when one regulatory body takes on the responsibility for regulating both aspects.

Key elements are:

- Nuclear safety regulations and practices;
- Radiation protection regulations and practices.

Discussion:

In 2002 ASN took on the responsibility of regulating radiation protection as well as its traditional role of regulating nuclear safety in France. Managing these responsibilities in France should be an experience from which others can learn.

The IRRS team believes that this is an opportunity that other Member States who are faced with the integration of previously separate responsibilities may wish to take advantage of. ASN had requested this merger for many years; it took a long time to achieve it, and ASN has identified three areas of progress.

1. Lessons learned from the incident in Tricastin have led to improvements in occupational radiation protection.

2. Radiation protection in medical practices and industrial practices: additional statistical studies were made on doses received and getting individual dose information.

3. The issuing of guides to improve the performance in the medical sector: ASN has used the experience gained with the NPP sector and applied similar approaches to the medical sector, e.g. looking at the training of people. ASN is also effecting improvements in radiation management aspects of the medical sector using, where applicable, experience feedback from nuclear installations.

In the field of nuclear installations, ASN established specific meetings with staff of EDF to include radiological issues. However, the experience has been that it is easy to harmonize rules and procedures, but more difficult to harmonize staff attitudes and create a good safety culture towards radiation protection.

ASN hopes to further and fully support the integration of nuclear safety and radiation protection aspects in the near future. In addition, the linkage between nuclear security and nuclear safety could be further clarified in France, where benefits may be achieved by having them more closely linked.

8.11. Response to nuclear renaissance

Background:

International, nuclear regulatory groups have been formed to address common problems and strengthen cooperation and coordination. Many vendors have evolved into global enterprises, and

large generating companies and management organizations now operate many plants. Multilateral R&D has become an important part of the future for nuclear energy. Advances in information technology and communications have led to stronger interactions between operating organizations, regulatory authorities, and concerned stakeholders, with greater public awareness of nuclear safety issues. However, great effort is needed for both emerging and mature nuclear Member States to ensure that necessary nuclear safety infrastructures are in place to maintain a viable nuclear safety programme.

Key elements are:

- Commitment to resource planning;
- Commitment to knowledge management;
- Assessment of workforce competencies to meet emerging technologies (R&D from the TSO or the regulatory body itself);
- Collaborative efforts with other regulators on the review of new designs and technologies.

Discussion:

Large vendors operating internationally may represent a new dimension and bring with it opportunities when reactor systems are operated and licensed in other countries. There is advantage in terms of effectiveness and efficiency in sharing information and safety analysis between regulators. Several countries represented in the IRRS team are now dealing with reactor designs that are also going through the licensing process in other countries. Many of these countries are working together to achieve effective and efficient delivery of licensing and nuclear safety.

International cooperation between nuclear safety authorities on new issues is progressing, but not as rapidly as some would wish. Finland is a good example of cooperation on the EPR. There are, however, still many aspects to discuss internationally among regulators regarding the licensing of new reactor designs.

There are two levels to consider in the licensing process – reviewing the design against standards (e.g. for safety analysis and safety reviews), and then the application of a country's regulatory approach. It is important to share the safety analysis and safety reviews carried out in different reactor areas (e.g. reactor physics) and to compare different approaches taken in different countries.

ASN also reported that it has a strong programme of exchanging experts and inspectors with different countries to improve and widen regulatory capability, both of ASN and other regulatory bodies.

8.12. Human resources and knowledge management

Background:

In many regions, the human resource of the nuclear community is aging. With the nuclear renaissance in some Member States there is a need for increased human resources. The need for knowledge management of the existing human resources and for knowledge sharing is recognized. The new move towards network building for global knowledge sharing and management is showing promising results. Efforts in this direction need to continue to ensure availability of resources. Also, facilities critical to the conduct of important safety research need to be preserved.

Key elements are:

- Plans to attract and retain staff;

- Existing strategies to identify, capture, and transfer knowledge internally and externally;
- National or regional training centres;
- Identified specialized skills and identified strategies to maintain and build competence;
- Appropriate emphasis on regulatory research and technical support organizations.

Discussion:

There are many discussions on personnel management and human resources issues among regulators. Each country has different approaches and issues. For example, the French civil service concept of rotation is not applied to the same extent in other countries. This leads to about 50% of ASN's staff changing jobs and possibly moving outside of ASN every 3 years. On the other hand ASN has people with longer experience including those who rotate between ASN and IRSN. Maintaining the regulatory competence levels of ASN in light of this policy of staff rotation is a recognized issue, and it is necessary to be confident that the transference of expertise can easily take place.

Hiring people for ASN is not a particular issue. Since merging nuclear safety and radiation protection in 2002, the size of the ASN staff has in four years been doubled without any difficulty.

In the US, NRC has hired over 200 in the last year, and approx 30-50 of them are fresh graduates and require substantial training and induction. Many of the remainder of those hired are very experienced and established in their careers.

One observation was that, because there was little recruitment some years ago (when people saw little future in the nuclear area), there is a generation missing with only senior and younger staff being present.

Considering the roles of ASN and IRSN, ASN needs to pay special attention to avoiding loosing internal competence and the necessary decision-making capacity in nuclear regulation. ASN recognizes this and is developing strategies to cope.

Many countries are considering the need to collaborate with competent TSOs that are based abroad, where the expertise has evolved on new or different designs, etc. This collaboration needs to be done carefully in order to maintain regulatory independence and capabilities.

9. TRANSPORT OF RADIOACTIVE MATERIAL: FOLLOW-UP TRANSAS MISSION

Background

The IAEA completed in 2004 a TranSAS mission on the implementation of the Transport Regulations in France. The Mission Report IAEA Safety Standard Application – TranSAS 6 *"Appraisal for France of the Safety of the Transport of Radioactive Material"* [1] describes this mission in detail.

The 2004 TranSAS mission resulted in 3 recommendations, 16 suggestions and 12 identified good practices. Therefore, the review of transport of radioactive material in the IRRS mission to France was covered as a TranSAS Follow-up, with the following objectives:

(a) To assess the progress made so far regarding the recommendations and suggestions; and

(b) To check if the identified good practices, in particular in the area of maritime transport, have been maintained.

These specific objectives were accomplished by interviewing personnel and reviewing documentation. The order of topics used in the TranSAS report [1] is followed to facilitate the follow-up to recommendations, suggestions and good practices.

ASN is working effectively on the implementation of the TranSAS recommendations and suggestions. The identified good practices are being maintained and, in some cases, enhanced.

In response to the recommendations and suggestions from the TranSAS mission, the staff for transport in ASN was increased by 1 person. Also, ASN evaluated the outputs from other TranSAS Missions (notably for Japan and United Kingdom) and has adopted a number of identified good practices in those countries.

The following gives details on the follow-up of recommendations and suggestions given in the TranSAS report.

9.1 Legislative and Governmental Responsibilities

Suggestion S16 - *It is suggested that memoranda of understanding be updated and reissued, when appropriate, to record the current names and responsibilities of ministers and agencies.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.75-4.78.

Follow-up status

A copy of a revised protocol DGSNR-DGMT [3] was provided, demonstrating objective evidence that this suggestion, S16, was fully implemented.

9.2 Authority, Responsibilities, Functions of Organization of the Regulatory Body

Suggestion S17 - *It is suggested that a review of the totality of the compliance assurance programme by the DGSNR, as the competent authority, may be beneficial, so as to confirm that all necessary aspects of the compliance assurance programme are in place and are fully effective (e.g. refresher training for both industry and inspectors, distribution of information to industry and more complete interdepartmental liaison).*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.109

Follow-up status

A procedure, based on the IAEA draft Safety Guide on Compliance Assurance [2, 4] was developed. The adoption of the memorandum of understanding by the competent authority of the UK [5, 6] is a strong indicator of the evolution from a practice to a good practice. The information and documentation provided by ASN constitute objective evidence that the suggestion S17, as described in the TranSAS Mission Report, is adopted and fully implemented.

Suggestion S18 - *It is suggested that a suitable protocol be developed and implemented to recognize the respective responsibilities and the range of separate and joint activities of the DTT and DGSNR relative to the safe transport of dangerous goods, including Class 7, radioactive material.*

BASIS

Details are provided in TranSAS-6 Mission Report – **§**4.110

Follow-up status

Based on the protocol [3] provided to fulfil S16, this suggestion is considered adopted and fully implemented.

Suggestion S19 - *It is suggested that suitable legal training for appropriate competent authority personnel be provided, in order to significantly contribute to the success of future legal actions pursued by the competent authority.*

BASIS

Details are provided in TranSAS-6 Mission Report – **§**4.111 and 4.112

Follow-up status

The IRRS Review Team was informed that expert legal support to ASN inspectors has been provided by ASN headquarters in Paris. The new TSN Law no. 2006-686 establishes the financial penalties that can be imposed by ASN, and a decree is to be issued to give inspectors appropriate empowerment. The existing approach to legal support coupled with the new Law is considered satisfactory for the purpose of this follow-up mission.

Suggestion S20 - *It is suggested that the DGSNR review and improve, if necessary, its arrangements for confirming the adequacy and completeness of the Quality Assurance programmes in use for all phases of the transport of radioactive material.*

BASIS

Details are provided in TranSAS-6 Mission Report – **§**4.113-4.114

Follow-up status

The development and distribution of a draft guide [7, 8, 9, 10, 11] for inspections in QA provides an indication that this action may evolve into a good practice. This suggestion is considered adopted.

Recommendation S21 – *It is recommended that the DGSNR`s convention with the IRSN for nuclear safety, transport and radiation protection should be reviewed, and an additional specification should be developed; this specification should clarify and record the current understanding of the completeness and recording of transport related assessment work carried out on the DGSNR`s behalf.*

BASIS

Details are provided in TranSAS-6 Mission Report – **§**4.115, 4.116

Follow-up status

Based on the information provided on Recommendation S26, this Recommendation is considered adopted and fully implemented.

Recommendation S22 – *It is recommended that the DGSNR should consider what an appropriate review programme for non-competent authority approved package design, manufacture and use would consist of, and how such a programme could be incorporated within its compliance programme.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.117 and 4.118

Follow-up status

The Compliance Assurance Programme [4], revision of 30 October 2006, addresses the packaging for which certificates are not required to be approved by the Competent Authority. ASN also developed a guide for the industry [13]. A guide for inspection was also developed [14, 15, 16]. From the information and documentation provided, it is concluded that this recommendation was implemented.

9.3 Authorization Process

Suggestion S23 - *It is suggested to continue with the efforts to minimize the application of special arrangement approvals, as indicated by the statistical data for 2003, and to take appropriate actions in order that fully approved or validated package designs are used.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.121

Follow-up status

The information provided by ASN [17, 18] constitutes objective evidence that the suggestion S23, as described in the TranSAS Mission Report, is fulfilled.

9.4 Review and Assessment Process

Recommendation S26 – *It is recommended that the DGSNR, supported by the IRSN, modify the review and assessment procedures in such a way that demonstration of compliance with each applicable requirement of the 1996 edition of the Transport Regulations is documented explicitly for design approvals, shipment approvals and special arrangements.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.131, 4.132, 4.133 and 4.134

Follow-up status

The development and implementation of a document [12] defining the scope of activities to be performed by IRSN as well as listing the requirements to be considered in the evaluation of a packaging design fulfils the needs identified in the TranSAS Mission Report. This recommendation is considered adopted and fully implemented.

Suggestion S27 – *It is suggested to develop and publish an application guide for design approvals, shipment approvals and special arrangements, in addition to the experience feedback document, to describe a complete and consistent format to reflect all applicable requirements of the 1996 edition of the Transport Regulations for such applications for approvals and to provide guidance on the contents of the corresponding safety analysis reports.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.131, 4.132, 4.133 and 4.134

Follow-up status

The publication of the guidance to applicants [19, 20, 21] fulfils the suggestion from the TranSAS Mission Report. Additionally, the compilation of findings from previous safety assessments seems to be very useful to applicants and may constitute an identified good practice.

Suggestion S28 - *It is suggested that the IRSN review the capability and the application of the available computer codes, and staff training on these codes, for different areas of package design assessment, to ensure a comparable standard and quality level of safety demonstration in all areas, when needed.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.135 and 4.136

Follow-up status

Regarding the capability of personnel to develop criticality studies ASN provided a letter sent by IRSN [22] stating that its staff has international expertise in this field. ASN has accepted the information provided by IRSN and considers this suggestion fulfilled.

Suggestion S29 - *It is suggested to review the current assessment practice of looking at quality assurance requirements in a general way during the approval procedure of the package design, in relation to looking at them in detail through later inspection procedures.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.137

Follow-up status

To fulfil this suggestion IRSN proposed to ASN an addendum to the applicants' guide [22]. A copy of this addendum was provided. This suggestion is considered adopted.

Suggestion S30 - *It is suggested to review the practice of handling design changes and modifications in such a way that, independent of the decision taken by the certificate holder on classifying the change being safety or non-safety related and independent of inspection activities, a complete and actual status of each packaging as used is maintained by the certificate holder and is available to the competent authority upon request.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.138

Follow-up status

The procedures and guides developed to fulfil suggestion S27 [19] are also applicable to this suggestion. This suggestion is considered adopted and fulfilled.

9.5 Inspection and Enforcement

Suggestion S32 - *It is suggested that the enforcement powers of local DNSR inspectors be reviewed, to consider legislation enabling them to directly serve a legal notice that would immediately prevent a non-compliant or unsafe process from continuing.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.150

Follow-up status

The information and document provided show that ASN has made use of its own cultures to deal with legal aspects involving inspections. The promulgation of the TSN Law 2006-686 changes the existing scenario but not enough to require - on a short term basis - a change in the existing culture. This local solution is believed to be satisfactory for the purposes of this follow-up mission.

9.6 Development of Regulations and Guides

Suggestion S33 - *It is suggested that the DGSNR post on its web site the available guidance material on radiation protection programmes produced by the NRPB, GRS and IRSN, in order to assist users in complying with the requirements.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.165, 4-166 and 4.167

Follow-up status

As suggested, the ASN website now provides information and guidance on radiation protection for transport. Links to NRPB (UK), IRSN (France) and GRS (Germany) are also provided. This suggestion is considered fulfilled.

9.7 Emergency Preparedness for Transport

Suggestion S42 - *It is suggested that the establishment of general international response agreements for the Mediterranean area be explored, so that the Mediterranean NUCMAR plan could be operated, if necessary, in a wider context.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.190

Follow-up status

ASN provided information on the agreements between France and Spain (Lion Plan) and the plan of cooperation between France, Italy and Monaco (L'Accord RAMOGE from 1993). The conventions signed in Barcelona (1976) and Malta (2002) are also applicable to this case. This suggestion is considered fulfilled.

Suggestion S43 - *It is suggested that the possibility be explored that the DAMGM collect the information on the transport of radioactive material that is available from the ports.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.192

Follow-up status

Currently the system TRAFFIC 2000 [23] for the control of goods in general is being used to concentrate information on maritime transport. This is made in accordance with the European Directive 2002/59/CE. This system is under modification and for the year 2007. It is expected that, once modified, this system will fulfil the suggestion.

Suggestion S44 - *It is suggested that the DGAC undertake a review of resources available to conduct compliance monitoring and inspections, in particular in the Paris region.*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.200, 201, 202, 203, 204, 205 and 206

Follow-up status

ASN informed the reviewer that letters [24, 25, 26, 27, 28] were sent to DGAC with an attached list of action, procedures and working instructions related to transport of radioactive material. At the time of the IRRS no answer from DGAC had been received. ASN has taken the necessary steps to implement the suggestion from TranSAS Mission. However, ASN needs to wait for the reply from DGAC.

Suggestion S45 - *It is suggested that consideration be given to the compilation of an audit form or check sheet for Class 7 inspections undertaken by DGAC inspectors*

BASIS

Details are provided in TranSAS-6 Mission Report – §4.200, 201, 202, 203, 204, 205 and 206

Follow-up status

See information provided to fulfil suggestion S44 and reference [29].

REFERENCES TO CHAPTER 9

[1] IAEA Safety Standards Applications “Appraisal for France of the Safety of the Transport of Radioactive Material”, TranSAS-6, Vienna 2004

[2] IAEA Safety Standards Series Draft Safety Guide TS-G-1.4 “Compliance Assurance for the Safe Transport of Radioactive Material” (DS 327) (to be published)

[3] Protocole DGSNR – DGMT du 30 juin 2006 “ relatif a l`organisation administrative concernant l`élaboration, l`application et le contrôle des règles de transport des matières radioactives par voie terrestre ou maritime”

[4] ASN Programme d’assurance de la conformité relative au transport des matières radioactives, DGSNR/SD1 no. 1-SD-PQ-29

[5] (DfT) United Kingdom-(ASN) France Memorandum of Understanding on Approval of Certificates relating to the Safe Transport of Radioactive Material for Civil Purposes.

[6] Minutes of the meeting on MOU DfT/ASN, held on Paris on 17 May 2006.

[7] [7] DGSNR Fiche de Constats – Surveillance des Transportes de Matières Radioactives et Fissiles à Usage Civil

[8] DGSNR Letter 0677/2006 on Contrôle dês transports de matières radioactives – elaboracion du programme prèvisional d’inspecion 2007

[9] Project (draft) ASN Support d’inspecion dês programmes d’assurance de la qualitè applicables au transport de matières radiactives

[10] DGSNR Letter 0538/2006 on Assurance de la qualité applicable au transport des matières radioactives

[11] Guide DGSNR/SD1/TMR/AQ Rev 0, Juillet 2005 “Guide relative à L’assurance de la qualité applicable au transport des matières radioactives

[12] Document cadre ASN-IRSN “Transport de Matières Radioactives”, version 1, Octobre 2006

[13] ASN Canevas d’inspection transport – Conformité dès colis non-agréés: colis industriels de type IP1, IP2, IP3 et colis de type A

[14] ASN/Guide/SD1/01 Project du 03/11/2006 Guide de l’ASN conformité dês colis non agréés

[15] DGSNR Letter 0793/2005 “Identification dès fournisseurs et fabricants de colis non agréés

[16] Annexe à la letter DGSNR 0793/2005 “Contenu d’un certificat de conformité à um modele de colis de type A ou de type industriel

[17] DGSNR Letter 0552/2006 “Modeles de colis agréés em vertu dês éditions 1973 du réglement de transport dês matières radioactives

[18] DGSNR Letter 0265/2006 “Demandes d’approbation d’expedition et d’agrément dês modeles de colis ou de matiéres à usage civil transportes sur la voie publique

[19] Guide DGSNR/SD1/TMR/REQ Révision 0 de mars 2006 “Guide du reuérant pour lês demandes d’approbation d’expedition et d’agrément dês modéles de colis ou de matières radioactives à usage civil transportes sur la voie publique

[20] Annexe 1 du guide du requerrant: Retour d’expérience dès points soulevés lors des expertises

[21] Annexe 1 du guide du requerrant: Canevas pour l’élaboration d’un projet de certificat

[22] IRSN Letter DSU/2006-098 Transport – suites de la Mission TranSAS de l’AIEA en France

[23] IRSN Letter DSU/2006-119 Transport – suítes données aux conclusions de la mission TranSAS

[24] TRAFIC 2000 “Système d`information sur le trafic maritime”

[25] DGSNR Letter to DGAC no. 0491/2006 “Préparation audit IRRS (2006)

[26] Annexe à la letter DGSNR 0491/2006 “Inspection Relative au Transport dês Matières Radioactives”

[27] DGSNR Letter to DGAC no. 0263/2006 “Contôle des matéries radioacctives par voie aérienne

[28] [27] DGSNR Letter to DGAC no. 0156/2006 “Transport des matéries radioacctives par voie aérienne – Surveillance dês prestataires de services em aéroport

[29] Guide DGSNR/SD1/TMR/AIR “Guide Relatif aux Exigence Reglementaires applicables au Transport dês Matières Radioactives em Zone Aeroportuaire

[30] ASN Project (draft) “Support d’inspecion transport – contrôle de la fabrication des emballages conformes à un modéle de colis agree

10. INFORMATION AND COMMUNICATION

GS-R-1 §3.3(6)

The IAEA has not yet developed specific guidance on information and communications to the public for use as part of IRRS missions. However the IRRS team has reviewed this area in response to the French Government's request to include information and communications in the scope of the mission.

Information and communications have been an important aspect of the French Nuclear Regulator's work since its first formation in the 1970s. The ASN's information and communications are primarily aimed at 3 groups of stakeholders – the general public, the public with some knowledge of nuclear safety, and the media. Also ASN is active in promoting its core values of independence, competence, stringency and transparency and hence enhancing stakeholder confidence.

The Decree of 13 March 1973, which created the Central Nuclear Installations Safety Department (SCSIN), responsible for supervising nuclear safety in France entrusted it with the role of "proposing and organising information for the public on safety-related issues". The Decree of 1 December 1993, which created the Nuclear Installation Safety Directorate (DSIN), reiterated this public information duty, in the same terms. The Decree of 22 February 2002, which created the DGSNR (General Directorate for Nuclear Safety and Radiation Protection), expanded this public information duty to cover the field of radiation protection. The DGSNR was then tasked with "contributing to informing the public on subjects related to nuclear safety and radiation protection". The 2006 TSN Act further confirmed this role as part of ASN's function.

In order to discharge these duties, the ASN uses various media and actions in an effort to provide the public with information that is easy to understand and accessible to the greatest number of people.

ASN has worked to expand the participation of stakeholders (including representatives of environmental protection associations and of industry or administrations and elected officials) in the drafting of regulatory texts of general scope. It also informs the public about how these texts are drafted and hence enables the public to give opinions on the drafts. As an example, the draft National Radioactive Waste and Reusable Materials Management Plan (PNGDR-MV) met this two-fold objective: it was prepared by a working group coordinated by the ASN and expanded to include various stakeholders and was placed online in the summer of 2005 so that opinions could be sent in to ASN's website, www.asn.fr. All the comments received were also placed online, as part of the debate on a major topical and social issue.

Other innovations on the ASN website in 2005 included the creation of a 'Press conferences' section, publication on the 'Regions' pages of information about ASN supervision of the nuclear power plants operated by EDF, the NuPEER international symposium of 22 and 23 June 2005 devoted to nuclear power plant ageing, a revamp of the 'Texts' section and an updating of the CLI section.

The ASN information centre offers the public access to all of ASN's publications. The public can also consult publications about nuclear safety, radiation protection and ionizing radiation published by the other stakeholders: Local Information Committees (CLIs), High Council for Nuclear Safety and Information (CSSIN), nuclear operators, IRSN and other technical experts, health safety agencies, radiology and radiation protection societies, professional associations, environmental protection associations, and so on.

ASN makes use of internal tools on how to communicate and inform the public and also what to communicate, such as guides for spokesmen and on policy issues. Externally they have an extensive web site, and publish an Annual Report and every two months the publication "Contrôle". Inspection findings as well as reports of events at BNIs are published on the web site and are seen by ASN as an important part of their enforcement and influencing strategy.

The team reviewing information and communications has come to a consensus that ASN's information and communication strategy represents international good practice and sees it as an important field to share among all member states.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 §3.3(6) states "*the regulatory body shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public".*

G39 **Good Practice:** ASN's information and communication strategy represents international good practice. It provides extensive information to all stakeholders, especially to the general public, the public with some knowledge of nuclear safety, and the media. Using this strategy ASN is promoting its core values of independence, competence, stringency and transparency.

G40 **Good Practice:** The particular use of a quite elaborate opinion survey, including a lot of discussions and face to face meetings with stakeholders, seems to be a very powerful tool to assess the impact of the information programme and is also a good way to obtain a performance indicator.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APPENDIX II – MISSION PROGRAMME

MISSION PROGRAMME		
Sunday, 5 November 2006		
14: 00 – 17:00	**IRRS Review Team entrance meeting at the ASN Headquarters**	
Monday, 6 November 2006		
09:30 – 12:30	**Entrance Meeting at ASN Headquarters** - Welcome and introduction - Opening remarks - IRRS remarks - IAEA experts introduction	Mr. A. Lacoste Mr. A. Gürpinar Mr. L. Creswell
14:00 – 16:00	**ASN presentations** - Working and domestic arrangements - Review areas - Self-assessment executive summary	Mr. P. Bordarier
16:00 – 17:30	**Experts and counterparts open discussion** - Identifying emerging issues - Planning for the interview sessions	Counterparts & IRRS Review Team
Tuesday, 7 November 2006		
08:00	Departure to Fontenay-Aux-Roses for the TranSAS follow-up mission	Mr. N. Bruno
08:30	Interviews at the ASN Headquarters	IRRS Review Team
17:00-19:00	IRRS Review Team Meeting	
Wednesday, 8 November 2006		
08:00	Departure to Fontenay-Aux-Roses	Mr. J. Misak Mr. R. D. Wendling Mr. P. Sajaroff Mr. Y. Ryu Mr. J. Zarzuela Mr. R. Jansen Mr. V. Neretin
09:00 – 17:00	Interviews at the ASN Headquarters	IRRS Review Team
17:00 –19:30	IRRS Review Team Meeting	
Thursday, 9 November 2006		
07:14	Departure to Dijon for on site inspection Interviews at ASN offices in Dijon	Mr. Y. Ryu Mr. R. Jansen
07:00	Departure to Nantes to observe radiography inspection preparation and night inspection	Mr. P. Sajaroff
07:00	Departure to Le Guichet To observe the research reactor inspection	Mr. B. Boger Mr. G. Lamarre Mr. L. Matta
07:00	Departure to Bourgoin to observe emergency exercise launch	Mr. C. M. Larsson Mr. T. Varjoranta
08:00	Departure to Fontenay-Aux-Roses	Mr. J. Misak Mr. R. D. Wendling
8:30	Departure for medical field inspection	Mr. J. Le Heron

MISSION PROGRAMME		
8:30	Interviews at the ASN Headquarters	IRRS Review Team
17:00 – 19:00	IRRS Review Team Meeting	
	Departure to Lyon to observe and inspection the day after	Mr. R. D. Wendling Mr. L. Jova Sed
Friday, 10 November 2006		
	Departure to Dijon for on site inspection Interviews at ASN offices in Dijon	Mr. Y. Ryu Mr. R. Jansen
	Departure to Nantes To observe irradiator inspection	Mr. P. Sajaroff
	To observe decommissioning Superphenix inspection	Mr. C. M. Larsson Mr. L. Jova Sed
	To observe nuclear plan inspection at Dampierre Plant	Mr. B. Boger Mr. D. Graves
08:00	Departure to Fontenay-Aux-Roses	Mr. J. Misak Mr. G. Lamarre
08:30	Departure for medical field inspection	Mr. J. Le Heron Mr. L. Matta
08:30	Interviews at the ASN Headquarters	IRRS Review Team
17:00 – 19:00	IRRS Review Team Meeting	
Saturday, 11 November 2006:		
07:30	Experts meet to go to ASN Headquarters	
08:00 – 10:50	IRRS Team Meeting at the ASN Headquarters	
11:00 – 17:00	Social event: sightseeing tour, lunch in a brassiere and private museum visit.	
Sunday, 12 November 2006		
DRAFTING REPORT AT REVIEWERS DISCRETION		
	Departure to Chalons-en-Champagne for site inspection the day after	Mr. C. M. Larsson Mr. L. Matta
Monday, 13 November 2006:		
08:00	Departure to Fontenay-Aux-Roses	Mr. J. Misak Mr. Y. Ryu Mr. P. Sajaroff Mr. R. Jansen
08:40	Departure to CAEN, interviews at the ASN offices on inspection	Mr. B. Boger Mr. G. Lamarre Mr. D. Graves Mr. V. Neretin
	NPP inspection (Nogent-sur-Seine plant) on discharge and waste management	Mr. C. M. Larsson Mr. L. Matta
08:30	Interviews at the ASN Headquarters	IRRS Review Team
17:00	IRRS Review Team Meeting	
Tuesday, 14 November 2006:		
17:40	Departure to Cogema La Hague for next day site inspection	Mr. B. Boger Mr. G. Lamarre

MISSION PROGRAMME		
08:00	Departure to Fontenay-Aux-Roses, to lead ASN interviews	Mr. P. Sajaroff Mr. R. Jansen Mr. Y. Ryu Mr. J. Zarzuela Mr. T. Yamada
08:30	Departure to the IRSN Headquarters	Mr. J. Misak
08:30	Interviews at the ASN Headquarters	IRRS Review Team
17:00	IRRS Review Team Meeting	
Wednesday, 15 November 2006		
08:00	Departure to Fontenay-Aux-Roses, to lead ASN interviews	Mr. G. Lamarre Mr. Y. Ryu Mr. R. Jansen Mr. V. Neretin Mr. J. Zarzuela Mr. T. Yamada Mr. P. Sajaroff
08:30	Departure to the IRSN Headquarters	Mr. J. Misak
08:30	Interviews at ASN Headquarters	IRRS Review Team
11:30	Departure to St. Quentin for medical inspection	Mr. J. Le Heron
14:00 – 16:00	IRRS Review Team Meeting and report drafting	
16:00	Finalizing of Mission Report	
Thursday, 16 November 2006		
08:00 –16:00	IRRS Review Team Meeting and report drafting	IRRS Review Team
16:00	Draft Mission Report handed to counterpart	
19:30	Social event: dinner at “Train Bleu”	
Friday, 17 November 2006		
09:00 – 11:00	Counterpart review of draft Mission Report	
11:00 – 17:30	Plenary discussions	
18:00 – 20:00	Exit meeting	
Saturday, 18 November 2006		
Departure from Paris		

APPENDIX III – SITE VISITS

1.	Service de médicine nucléaire, Groupe Hospitalier
2.	Service de Radiologie Viscérale et Vasculaire, Groupe Hospitalier Lariboisière
3.	Radiotherapy Service, Centre Hospitalier St Quentin
4.	"Fontenay-Aux-Roses"
5.	ASN offices in Dijon
6.	Radiography inspection preparation and night inspection in Nantes
7.	Research reactor inspection, Le Guichet
8.	Irradiator inspection
9.	Decommissioning, Superphénix inspection
10.	Nuclear plan inspection, (Dampierre plant)
11.	NPP inspection (Nogent-sur-Seine plant) on discharge and waste management
12.	Waste repository inspection, Chalons
13.	Research reactor: OSIRIS facility
14.	COGEMA LaHague fuel cycle facility

APPENDIX IV: ROLE AND POSITION OF IRSN

IRSN is the technical support organization for ASN, and provides the review and analysis of technical issues as requested by ASN. Given the close relationship between ASN and IRSN, and the importance of the technical services provided by IRSN, the IRRS team felt it was important to include information about IRSN and its relationship with ASN.

IRSN is a large public organization with approximately 1650 employees, with about 1000 of these being scientists. There are 3 main directions of IRSN activities:

- Research;
- Technical support (to the Ministry of Defence, the Ministry of Environment and ASN);
- Public service mission (e.g. environmental monitoring, national database of exposure of workers).

IRSN's total annual budget is about 300 MEuro, with more than 80 % of this financed from the state budget through the Ministry of Environment. The remaining 15-20 % of the budget is from other resources – half of that is from EU projects, projects from other countries (Japan, US-EPRI, DOE) and also EDF, and the other half is covered by contracts mainly for radiation dosimetry of workers, and, for example, work for RISKAUDIT. About 50 % of the total budget is used for financing the research, and the other 50 % for technical support. Financial resources from the state budget are internally distributed for various tasks by the Board, with participation of representatives from various ministries.

Any technical support contracts for licensees are absolutely excluded, and are not possible even for nuclear operators abroad. As far as the EDF contribution to the budget is concerned, this is very small (2 % at present) and is decreasing with time. The EDF contribution is used for financing the research only. It can not be excluded that research results are used by EDF in their applications to ASN, but interpretation of results is under the responsibility of EDF. This may be the case for criticality calculations for specific geometries and material properties, where IRSN expertise is unique in France.

There are 7 scientific directions covered by IRSN's work:

- Existing NPPs equipped with PWRs;
- Future nuclear facilities;
- Radiation protection;
- Security issues, including non-proliferation;
- Emergency provisions;
- Low doses impact;
- Medical radiation protection.

Future research directions are first proposed internally by IRSN based on their previous activities, information from the international community, and operational experience feedback. These directions are then specified in the 5-year framework contract. ASN can influence selection of research work through their representation on the Board, but until now there have not been many specific requests from ASN.

Relations between ASN and IRSN are formalized in a number of ways:

- The charter (code of practice), which specifies basic rules for interrelations;

- Framework agreements, specifying field of activities and priorities for next 3 years;
- Annual protocols, with detailed tasks for one year;
- 3 high-level meetings per year at the level of directors, devoted to:
    - evaluation of results;
    - determination of priorities;
    - resolution of difficulties and disagreements.

The scope of IRSN activities as a TSO for ASN includes:

- Analysis (technical examination) of safety files;
- Emergency support ands crisis management;
- Support in inspections (acting together with ASN inspectors, with only an advisory role);
- Cooperation on writing of decrees, regulations, guides; for some regulations (radiation protection) their opinion is legally required;
- International cooperation.

As far as human resources available for IRSN are concerned, this year there are more than 370 equivalent experts working for ASN, and the total budget for ASN support this year is 69.4 MEuro.

Distribution of manpower for different tasks is approximately as follows:

- 180 – PWR;
- 20 – research reactors, including Phenix;
- 100 – fuel cycle facilities, including ITER;
- 50 – radiation protection;
- 16 – transport;
- 6 – International cooperation.

The resources of approx 70 MEuro correspond to the given number of experts and are practically constant. To a large extent the resources assigned are independent of the specific work requested by ASN. There are no additional specific small contracts signed for each task. Therefore, real motivation for good IRSN performance is based on a quality management system, aimed at customer satisfaction, professionalism in every kind of activity, and optimal benefit for the society as a whole from all different activities. IRSN is ISO 9001 certified. In the future, according to the recently issued legislation, IRSN will be subject to the external scientific evaluation by a panel of independent experts. Currently, this role is partially performed by their scientific committee, nominated by the ministers.

Transparency is considered an important component of their work. Information from IRSN is available on their web site which has about 1 million hits per year.

Inside IRSN, experts are assigned responsibility for certain installations, but composition of a team for each task is changed according to the nature of the problem. Requests from ASN are classified into 3 categories: A – to be addressed immediately, B – with specified time limit to be followed to the extent possible, C – less urgent tasks. Joint meetings are used when re-prioritization is needed, e.g. due to the fact that available resources are not sufficient to perform the work. Part of the work can be contracted to other organizations, e.g. universities. Basic safety rules and recommendations by standing groups are used as a basis for the evaluations. Evaluation is not legally based on the available guides; and

there is strong reliance on expertise. IAEA Safety Standards are not considered to be detailed enough to be used as a basis for evaluation, with the exception of the standards for transport and radiation protection. Some computer codes used for computational analysis are different from the codes used by EDF, but in other cases the same codes are used.

Independence of the decisions made by IRSN is further confirmed by standing groups of experts (20 – 25 people in each group). The role of IRSN is to examine the problem and prepare the report for the standing group, which formulates the advice for ASN.

Legal responsibility of IRSN for their advice is currently under discussion, but they believe that they are responsible to some extent.

There are certain IRSN activities to enhance ASN's capability as an 'intelligent customer'. On average, about 60 people from IRSN temporarily work for several years in ASN. Specific training is offered every year to ASN staff. For some kinds of work, e.g. for examinations performed by a regional inspector in the radioactive waste area, written internal guides have been developed.

In the discussion IRSN identified several areas where they consider that more effort and resources are needed, but their opinion is not always supported by ASN. Examples of such areas where more effort and resources are needed are human factors, the cost-benefit approach and its impact, reduction of safety margins, safety issues related to new reactor types – generation IV reactors including fast reactors, ITER, safety related software, and unresolved severe accident issues.

IRSN considers as important sources of their expertise the research, operational experience feedback and cross-fertilization among various areas. Therefore they are convinced that any artificial separation between their research and TSO activity would be counter-productive. Feedback from events from NPPs is an essential contribution to their expertise. IRSN receives copies of all reports sent by operators to ASN. There are about 800 events reported from PWRs every year. All events are analysed and discussed in meetings at different levels: internally in IRSN every week, periodic meetings every 3 months with the participation of ASN and EDF, a meeting every 3 years summarizing experience and long-term analysis during PSR. Summaries and lessons learned are included in the 3-year reports. The events are stored in an IRSN database, which is not directly accessible to ASN. IRSN also sends selected events to the IAEA IRS database.

Managers of IRSN believe that the current system of organization of TSO work is appropriate and should only be adjusted to be in compliance with the new law. Of course, there should be continuous effort to improve their performance.

APPENDIX V – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Lead Counterparts
	Legislative and governmental responsibilities	• L. Creswell A. McEwan	• **President** • DG/DGA • Pinel • Bizet • Leblanc
	Responsibilities and Functions of the Regulatory Body	• L. Creswell • A. McEwan	• **President** • DG/DGA • Pinel • Bizet • Leblanc
	Organization of the regulatory body	• K. Abe • T.. Yamada • J. P. Samain	• **Bordarier** • Jubin • B. Bobe
	Activities of the Regulatory Body	• J. Misak • J. Le Heron • P. Sajaroff • R. D. Wendling • V. Neretin (Observer) • T. Varjoranta • G. Lamarre • B. Boger • Ryu • J. Zarzuela • R. Jansen (Observer) • L. Jova Sed	• L. Foucher • Ph. Bodenez • D. Landier • S. Rodde • J-L. Godet • D. Krembel • M. Perrin • G. Rudant • D. Conte • A. Bizet • J.M. Leblanc • M. Baudoin

Item	Subject Area	IRRS Experts	Lead Counterparts
		• L. Matta	• J. Aguilar • J. Devos • J. Rieu • D. Conte • D. Landier • J-R. Jubin • M. Stolz • J. Collet • F. Feron • P. Charpentier • J. Aguilar
	Emergency Preparedness	• C. M. Larsson • T. Varjoranta	• B. Verhaeghe
	Infrastructure for radioactive waste management	• R-D. Wendling • L. Matta • L. Jova Sed	• **Stoltz** • Feron • Collet
	Management System for the Regualtory Body	• T. Varjoranta	• P. Bordarier • J-R Jubin
	Policy Issues	• C. M Larsson • T. Varjoranta	• President • J. C. Lachaume • P. Bordarier • J-R Jubin
	Transportation of Radioactive Material: Follow-up TranSAS	• N. Bruno	• J. Aguilar • M. Baudoin
	Information and Communication	• L. Creswell • A. McEwan	• Delmestre • Chanial

APPENDIX VI – RECOMMENDATIONS/SUGGESTIONS/GOOD PRACTICES FROM THE IRRS MISSION

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
A	Legislative and governmental responsibilities	*R1*	*In order to fully clarify and enhance its independent status, and put into place the new enforcement powers, ASN should as soon as practicable fully implement the requirements and the powers given to it by the new TSN 2006 Act through elaboration and implementation of the necessary Decrees and Orders.*
		R2	*Although ANDRA has some responsibility in this area, ASN should continue its work to clarify and formalize the arrangements to ensure safety e.g. for "orphan" sources.*
		G1	*ASN makes extensive use of independent expert advisory committees on a variety of topics and themes in many areas. These advisory committees include experts from other countries.*
		R3	*ASN should consider development of its input into and formal monitoring of research and development in nuclear and radiation safety.*
B		*G2*	*The environment law provides for Public Debate and Public inquiries on the establishment of major facilities. ASN provides full information e.g. to Local Information Committees as part of this process.*
		S1	*The ASN should interact with the administrative authority which controls the funds for radioactive waste management and decommissioning to make technical competence available and to*
		R4	*The clarification of interaction between the Ministry of Labour and ASN concerning the radiation protection of workers should be carried out.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
C	Responsibilities and functions of the regulatory body	R5	*ASN has many orders and guides under review and in preparation to further incorporate IAEA standards and WENRA reference levels. This work should be completed as soon as practical as part of the renovation of the French nuclear and radiation safety regulation. This should also create a single, comprehensive set of orders and guidance that are clear and useful to all parties involved.*
		G3	*Reasons for the rejection of a submission are given not only in ASN decision letters, but also are published on the ASN web site.*
		R6	*ASN should initiate and make arrangements to improve the timely reporting of occupational radiation exposure doses for oversight and analysis of radiation protection practices. [Dose information should be made available in a timely manner to individual employees and employers and ASN to help ensure optimization and limitation of radiation exposures].*
	Organization of the regulatory body	R7	*To avoid too fast a turn-over leading to too many people leaving the ASN after a short period, ASN should organize and foster more possibilities for rotation of positions within ASN.*
		G4	*The training programme is mature and well developed.*
		G5	*The involvement of ASN in the framework of international cooperation is quite active and exhaustive and bilateral agreements are well developed.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
D	Authorization, review and assessment and inspection and enforcement	S2	*ASN should formalize the process already established in letters to the licensee into generally applicable regulations or guides describing the format and content of documents to be submitted by the operator in support of applications for authorization, as well as the principles and criteria to be followed. This suggestion applies in particular to the content of Safety Analysis Reports and General Operating Rules, with due consideration of recently issued IAEA Safety Standards and lessons learned from the WENRA harmonization process.*
		S3	*ASN should consider replacing the existing uniform format of approval letters broadly used for many different authorizations by a system of authorizations differentiated according to the subject and importance of the authorization.*
		S4	*ASN internal procedures describing the process of authorization should be further improved or developed in order to optimize participation of various organizational units in the process, to ensure time limits are set up for processing the authorization, and to fix the rules for recording and archiving justifications for decisions made during the authorization. These internal procedures will also contribute to harmonization of approaches among the sub-directorates.*
		S5	*ASN should continue in collecting experience with internal authorizations and generic authorizations, currently demonstrated as an effective way for enhancing the licensee's prime responsibility for safety, in order to allow for future broadening of their scope without compromising regulatory responsibilities and to take account of the possible impact of competitiveness in the nuclear power industry.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S6	*Based on the positive experience gained with the authorization of the EPR reactor in France, ASN should formalize a pre-certification process for possible future generic (site independent) reactor designs in order to provide for high quality and reasonable time of licensing.*
		G6	*ASN has established a sophisticated system of authorizations adequately covering all stages and activities related to the lifetime of a NPP with a graded approach, with due account given to the complexity and safety impact of each activity. This includes involvement of the public in the authorization process.*
		S7	*The timely completion of IRSN reviews was raised as an area requiring improvement. As an example, ASN has performance targets for response to operators of authorization requests. However, there is no means by which ASN can require complementary performance measures of IRSN. ASN may consider further refining these key interlinkages with respect to review and assessment performance management with IRSN.*
		G7	*The internal authorization process permits licensees to undertake activities outside the principal authorization based on guidance principles issued by ASN to the licensee. All proposed authorizations are passed to ASN staff in advance for their review and concurrence.*
		S8	*ASN may want to consider formalizing their review and approval programmes for financial guarantees and the associated preliminary decommissioning plans in advance of initial authorization for new BNIs.*
		G8	*ASN internal performance indicators are used as a tool for on-line checking of status of individual regulatory activities with a positive effect on preventing delays in issuing authorizations.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S9	*ASN should reconsider the categorization of facilities using X-rays in interventional procedures.*
		G9	*While relatively new to authorizing the use of radiation in medical practices, ASN has developed clear requirements for what needs to be submitted, including details to demonstrate safety, and is developing clear procedures for how the information is to be assessed.*
G		S10	*Notwithstanding the Good Practice G9, it is suggested that ASN completes the development of its internal procedures (nuclear medicine) to cover all medical practices, considering its own experience feedback.*
		R8	*Considering the decision to change the role of AFSSAPS in authorizing the manufacture and distribution of sealed and unsealed sources, and X-ray generators (with likely transfer to ASN in 2007), ASN will need to develop technological surveys, in collaboration with IRSN, to assess the safety of new medical devices, using current international standards for radiation safety.*
		R9	*The relationship between the ASN authorization for use and the future INCa authorization for a health practice (e.g. cancerology) must be clarified and formalized.*
X	The review of the management system	S11	*The ASN, through its new powers, should issue technical decisions that set radiation safety standards for radiology, nuclear medicine, brachytherapy and external beam radiotherapy installations.*
		S12	*ASN might wish to review whether the documentation and controls needed for the declaration of a dental X-ray practice should be the same as for the authorization for a medical practice.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		G10	*ASN has developed application and declaration forms that provide clear guidance on the format and content of documents to be submitted by the operator in support of applications for authorization or for notification*
		S13	*Notwithstanding Good Practice G10, it is suggested that, for the purpose of simplifying the process for users, ASN reconsiders some of the information it currently requests.*
		G11	*ASN has developed procedures for processing applications for authorization that result in either the granting of an authorization or its rejection, including the basis for the decision. Templates for authorizations have been developed for the respective areas of medical uses of radiation.*
		S14	*It is suggested that ASN reviews the information it currently requests for amendment or renewal of an authorization or amendment to a declaration.*
		S15	*ASN should consider sending a reminder letter to licensees prior to the 6 months before the expiry date of the authorization.*
		R10	*ASN should adapt its existing guidance to form formal procedures in the framework of its management system, covering the use of radiation sources in all practices connected with industry and research authorized by SD1.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		G12	*ASN suggests submitting technical modifications of minor safety significance in nuclear facilities undergoing decommissioning to an internal authorization process of the operator under the close scrutiny of the regulatory body. This is considered good practice beyond the requirements of IAEA safety standards on decommissioning, because decommissioning is a chain of modifications and the assessment of modifications along the standards of the regulatory body strengthens the safety conscience of the operator.*
	Review and assessment	R10	*ASN shall demonstrate that they have the necessary qualifications and expertise to be accepted as a Notified Body for N1 Class equipment as required by EU directive 97/23/CE and to comply with international standards.*
		S16	*In light of improving effectiveness and efficiency in the safety review process, ASN:* • *should make more comprehensive use of the graded approach, in particular for general operating rules;* • *should ensure that external technical support is available and utilized as necessary to support the variance in the regulatory body activities, including identification of acceptable consultants;* *Should Establish An Internal Guideline For Review And Assessment Of PSR.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S17	*ASN should consider establishing guidance that ensures that those subjects of NS-G-2.10 that will be reviewed outside of PSR are accomplished with the same thoroughness and with at least the same frequency as in other formal review processes. The reason for exclusion from PSR should be well justified. ASN should reevaluate the extended implementation of modifications following a PSR, taking into account an acceptable ranking method for implementing modifications. The results of this then should be incorporated in the guideline.*
		G12	*The process for approving exemptions from the technical specifications and documentation for the decision is thorough and comprehensive and can be considered as a good practice.*
		S18	*ASN should review and compare the ageing management assessment methods used by each SD in order to ensure consistency.*
		G13	*ASN has developed a comprehensive programme for monitoring, tracking and evaluating thermal transients during the life of the plant.*
		G14	*The review and assessment process, including documentation, of the design, construction, manufacturing, maintenance and operation for primary and secondary components of NPPs can be considered as a good practice.*
		S19	*ASN should require licensees to do an integrated assessment of all events and report this to ASN periodically. ASN should increase the sources of evaluated foreign events.*
		G15	*The French PSR approach, using extensive advice from the TSO and the Standing Committees and applying it with the same rigour to all Basic Nuclear Installations, is considered a good practice.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		G16	*The annual statistical analysis and documentation of events for research reactors and fuel cycle facilities provides a valuable input to the regulatory programme.*
		G17	*In the context of medical exposures, the French regulatory framework establishes appropriate responsibilities and requires personnel (medical practitioners, medical physicists, radiation protection officers) with appropriate training and qualifications. There are specific requirements for training on patient radiation protection.*
		R11	*ASN should consider lobbying government and the appropriate ministries with a view to further resources being made available to increase the number of medical physicists.*
		G18	*The French regulatory framework clearly establishes the principle of justification in medical exposures and, further, requires records to be kept in the patients notes for such justification. The professional societies are developing guidance on justification.*
		S20	*That ASN encourages and assists the professional societies so that publications are available on justification for all uses of radiation in medicine. ASN should explore means for ensuring adherence to the guides.*
		R12	*That the ASN sets up a system to ensure appropriate justification of persons exposed to radiation as a result of being in biomedical research trials, where the use of radiation is not the focus of the research.*
		R13	*That the ASN ensures that the review of medico-legal uses of radiation takes into account the current international recommendations of the IAEA, WHO*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		R14	*That ASN performs a review of all the orders and circulars and the UTE standards to ensure that the technical requirements for ensuring optimization of medical exposures in external beam radiotherapy, brachytherapy, nuclear medicine, interventional radiology, medical radiology and dental radiology meet current international standards, including the IAEA BSS and other documents.*
		S21	*That ASN considers means for extending to existing X-ray machines (especially those used primarily for children) the commendable regulatory requirement for new X-ray machines to be fitted with dose measuring devices.*
		G19	*The regulatory requirement for reporting small annual patient dose surveys to IRSN as part of implementing DRLs is to be commended.*
		S22	*ASN should assist IRSN in exploring all means to help users comply with the requirement for reporting doses. ASN needs to establish with IRSN how the collected information is to be fed back into the regulatory programme.*
		G20	*The regulations require that patients undergoing diagnostic and therapeutic procedures using radionuclides must be given oral and written guidelines on radiation protection that are of use to the patient, his/her relations, the public and the environment.*
		S23	*That ASN works with the appropriate bodies to ensure that harmonized guidance for patients undergoing diagnostic and therapeutic procedures using radionuclides are issued as soon as possible.*
		S24	*That ASN should considers carefully, taking into account the type of medical exposure, what information is required to be kept so as to avoid an unnecessary administrative burden on the medical practitioner.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		G21	*ASN has taken appropriate steps to investigate reported accidental medical exposures, to widely disseminate information on the accidents, to solicit input for further improvement from licensees and professional societies, and to remind licensees of the existing regulatory requirements.*
		S25	*ASN investigates all means of making licensees more aware of the need to immediately report any accidental medical exposures, and why such immediate reporting will help radiation protection.*
		G22	*The regulatory activities performed by SD1 in industry and research are covering all these sections of GS-R-1.*
		R15	*ASN should consider inclusion of doses to the critical group from Basic Nuclear Installations in its Annual Report as well as descriptions of their meaning in terms of public health protection, and should assess the cause for differences between sites and different operational years.*
		S26	*For coherence and consistence, the periodic review and assessment (PSR) of the radioactive waste management facilities should be considered and included in the proper regulations for all type of facilities operating in the country; no matter if they are INB, ICPE or activities authorized according to Art. L.1333.4 of Code of Health. The PSR should be commensurate with the hazards posed by the installation and should take due account of the magnitude of the waste study, likely period of storage, the preferable use of passive safety features, the potential for degradation during that period and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		G23	*As in France nuclear facilities under decommissioning stay to be BNIs until they are released from regulatory control, they are subject to the requirement of a PSR every ten years. The process of internal authorizations even requests an update of the safety report every 5 years. This is considered good practice exceeding the requirements of IAEA safety standards on decommissioning, because the status of facilities changes considerably under decommission. In view of a time frame of about 20 years for the dismantling a complete assessment of the achieved status every 5 years seems to be adequate.*
	Inspection and enforcement	S27	*ASN should formalize the way of considering use of the results of periodic safety review, as well as operational experience in the development of BNI inspection programmes.*
		S28	*ASN should consider a formal periodic assessment of the inspection programme to evaluate its continued effectiveness, including consideration of risk informed insights.*
		S29	*ASN should further develop guidance for providing inspection oversight of human factors, human and organizational performance, and safety culture areas of their mandate.*
		G24	*ASN inspectors develop detailed agendas based upon off-site preparation activities that are used to facilitate on site inspection conduct.*
		G25	*ASN inspectors document inspection findings in at least 3 documents related to an inspection. Documentation of inspection results is readily retrievable for use in inspection programme development as well as serving as a readily available resource for recalling the*
		G26	*ASN has a robust and comprehensive accreditation programme for its inspectors.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		R16	*ASN should provide guidance to the inspection staff on how to determine the relative seriousness or significance of non-compliances and how to resolve identified issues of minor safety significance, such that an appropriate and consistent level of enforcement action can be applied.*
		R17	*ASN should develop the necessary enforcement tools and implementation guidance to effectively and consistently implement enforcement sanctions commensurate with the seriousness of the non-compliance.*
		G27	*Given that the regulatory system for radiation protection in medical exposures places significant reliance on approved persons and organizations performing radiation protection controls, it is commended that ASN has a system for inspecting the activities of such organizations, with feedback into their authorizations.*
		S30	*That ASN ensures that AFSSAPS takes note of the findings of ASN inspections in the AFSSAPS processes for approval and inspection of organizations performing the quality controls on medical devices required by the AFSSAPS decisions.*
		G28	*ASN is to be commended for developing in-depth guidelines for the conduct of its inspections in medical practices using radiation.*
		S31	*ASN is urged to complete the inspection documentation to cover all uses of radiation in medical practices (i.e. concerning conventional radiology and brachytherapy).*
		S32	*That ASN but extends the scope of its radiotherapy inspections to include organizational and human factors as presented in the IAEA Safety Series Report 38.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S33	*That ASN reconsiders the relative merits of inspectors performing technical measurements during a pre-authorization visit.*
		R16	*That ASN reconsiders the current frequencies for inspection of medical facilities using radiation, taking into account current international standards and good practice, in particular for interventional radiology and radiotherapy.*
		S34	*ASN should complete the development of formal procedures to analyse inspection findings and to incorporate these findings into the appropriate regulatory processes.*
		R17	*That ASN develops and implements a formal enforcement policy that covers the use of radiation in medical practices.*
		G29	*a) The preparation of inspections prior to their execution; and, b) the explanations and information provided by ASN inspectors to the operator at the end of inspections on identified good practices and deficiencies or deviations.*
		R18	*ASN should prepare more detailed guidance or procedures addressed to inspectors establishing in writing how they must proceed.*
	Regulations and guides	R19	*ASN should undertake a project to review in a systematic way the present requirements and guidance for facilities and activities other than NPP, in order to produce a more consistent assembly of regulations.*
		R20	*ASN should issue a generic requirement to facilities and activities to establish a management system, graded according to the safety significance and complexity of the facility and/or activity.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		G30	*The Law 2006-686 on "Transparency and Security in the Nuclear Field", through the instrument of the periodical safety review establishes a method for requesting improvement in the safety level of the installation.*
		S35	*That the scope, content and process of PSR, currently reflected in part in direct letters addressed by ASN to the utilities be described in an appropriate requirement or guidance.*
		R21	*ASN should formalize through appropriate guidance the spelling out of acceptable criteria for the process of modifications.*
		S36	*A general policy for the utilization of PSA or probabilistic studies, as applicable with a graded approach, should be established at nuclear installations and the corresponding guidance should be elaborated and published.*
		S37	*ASN should complete its present process of producing regulations and guides on analysis of operational experience.*
		S38	*That what is presently requested to the operating NPP regarding the severe accident is described in an appropriate requirement or guidance.*
		S39	*ASN should use its new powers to issue a set of technical decisions, after appropriate consultation and review, to give a coherent and harmonized set of regulatory requirements for authorized and declared practices using radiation for medical exposures based on current international standards such as those of the IAEA.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		R22	*That ASN completes the development of guidance on regulatory compliance for all areas of radiation use in medical practices. That the ASN should also consider the IAEA safety standards and guidance when developing regulations and guides.*
		G31	*The regulatory activities performed by SD1 with respect to industry and research are covering these sections of GS-R-1.*
		R23	*ASN should be involved at an appropriate level in the general revision of the regulation on polluted sites undertaken by the Ministry of the Environment that should provide a specific regulation on the remediation of polluted sites contaminated with radioactive materials. The new regulation should follow the recommendations of the International Standards. In this process it will be important to consider that before the formal termination of the remediation programme and the release from further responsibilities of the organization responsible for implementing the remedial measures, compliance with initial criteria shall be verified and the termination should be routinely subject to the approval of by the regulatory authorities.*
		G32	*The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes now comprehensively provides the necessary legal and regulatory framework in the field of radioactive waste management (including disposal), decommissioning and remediation.. This is considered to be good practice.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		R24	*ASN should coordinate with the Ministry of Environment the establishment of common approach for all disposal facilities that may dispose of radioactive waste general safety requirements and regulatory regime. In this regard the regulations should be developed or reviewed to be approved and implemented according to a schedule set up by the National Plan for the Management on Radioactive Material and Waste*
		S39	*ASN should within the framework of the new waste law consider the inclusion of a radioactive waste classification scheme (or schemes) or at least the basis for it in the radioactive waste management regulation. This classification scheme should consider the National Plan on Radioactive Waste Management actually in elaboration.*
		R25	*The dose constraint principle is considered in the regulations for the geologic disposal. The ASN should consider extending this concept to other areas and practices in order to communicate that the derivation of limits, and the optimization procedure, originates in a constraint that has been derived to safeguard that the dose limit of 1 mSv will not be exceeded.*
		R26	*ASN should coordinate with the Ministry of Environment the regulation of radioactive waste management to ensure the necessary consistency between the different regulations, whether they are issued by ASN or the ministry for the environment for ICPEs. It is recommended to include all activities and facilities present in the country and not only BNIs. Probably this may be organized in the framework of the National Plan for the Management of Radioactive Material and Waste.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S40	*ASN should consider to issue in a short term a regulation covering the design and construction of a radioactive waste storage facility, the likely period of storage, the preferable use of passive safety features, the potential for degradation during that period and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate.*
		G33	*The way the ASN is regulating, giving quantitative guidance for discharge of short lived radionuclides and controlling the discharges of installations other than BNI.*
		R27	*The ASN (in coordination with the Ministry of Environment) should establish generic reference (intervention) level, or generic safety criteria for aiding decisions on remediation and allowing to the establishment of the optimum strategy for facilities other than BNIs.*
		S41	*ASN should develop the regulations needed to support the decommissioning process from the design stage till the shutdown and decommissioning of different facilities.*
		S42	*Suggestion: ASN should clarify the policy on clearance, and communicate to interested parties including the public that, although declassification does occur, this is done whilst applying highly restrictive approaches and guidelines to safeguard public health.*
		S43	*Consideration should be given in guidance and codes of practice to the use of constraints, which are practice-specific.*
		R28	*The ASN should consider a requirement for authorized establishments to develop quality assurance systems.*
		R29	*The ASN should introduce regulatory changes so that passive dosemeter personal dosimetry results are promptly communicated directly to monitored individuals, the ASN, and employers.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
	Emergency preparedness	S44	*ASN should continue its work towards an upgrading of post-accident planning, taking into account the specific local and national conditions, that can couple with the off-site emergency plans that are already available for a large number of sites.*
		S45	*ASN should introduce a systematic and traceable training programme for the staff allocated to key functions*
		S46	*ASN should seek to facilitate and accelerate, to the extent possible, communication with the IRSN to reduce the risk that relevant information for ASN's capacity to provide advice to the prefect is delayed.*
		S47	*ASN should review its own capability to assess the situation independently of the IRSN.*
		G34	*The number of drills per year involving BNIs is very high and considering the relative similarity of French NPPs, the level of knowledge and experience on how to act in a nuclear emergency is very high. The response time to get the emergency centre operational is very short*
		G35	*An ambitious and well thought through planning for the handling of 'un-planned' events, such as the handling of orphan sources, is in place.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
	Infrastructure for radioactive waste management	G36	*ASN played a very proactive role in the elaboration, discussion and approval by the Government of the 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes. At the same time ASN took the lead in the elaboration of the first draft of the National Plan for Radioactive Waste Management, which includes NORM and TENORM which should be presented to the Government for approval before 31 December 2006, and that should be updated every three years for all kinds of radioactive waste streams.*
		G37	*ASN has contributed to determine whether any intervention is needed for reasons of radiation protection, bearing in mind that the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention. A lot of work has been done to identify situations requiring remediation actions.*
		S48	*The ASN should continue its efforts to coordinate with the Ministry of Environment the establishment of a common regulatory regime for the remediation of contaminated areas with radioactive materials including the safety of remediation actions that are carried out under the control of the prefect and inspectors of ICPEs (Installations Classified on Environmental Protection Grounds). The ASN should also be involved in the changes of the control of this kind of remediation, in relationship with DPPR at the ministry of environment.*
		G38	*The establishment by ASN of a list with the qualified organisations capable to evaluate the impact of existing chronic exposure scenarios and making recommendations to the authorities regarding actions to be carried out is considered a good practice.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
	Management system for the regulatory body	R33	*In light of ASN reorganization and management responsibility, the new Commission and ASN senior management should establish and document a policy and demonstrate commitment to establish, implement, assess and improve ASN's management system.*
		R34	*The development of the ASN MS should be continued. As one of the next steps, a master plan with major milestones, time schedules and resource allocations should be prepared and implemented to guide the systematic development of its MS. The plan should address, inter alia, issues discussed above and the three main dimensions of the management system,* *d. ASN's management system applied in-house,* *e. ASN's oversight of licensees' management systems, and* *ASN's oversight of TSO's and contractors' management systems.*
		R35	*In light of high staff turn over, including at management positions, regulatory needs related to the potential future developments in the use of nuclear energy, and competence as one of its core values,* - *ASN should reconsider its human resource strategy in order to ensure ASN's long term competence and the effectiveness and efficiency of the competence building efforts;* *ASN should ensure that the individual competence requirements (qualifications, education, experience) for each position in the organization are considered in a graded manner (relevance to safety), and that requirements are documented and followed.*
		S49	*In light of ASN's efforts to ensure greater consistency with IAEA safety standards, the requirements of GS-R-3, e.g. those related to safety culture, should be formalized, applied and enforced by ASN.*

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
	Information and communication	G39	*ASN's information and communication strategy represents international good practice. It provides extensive information to all stakeholders, especially to the general public, the public with some knowledge of nuclear safety, and the media. Using this strategy ASN is promoting its core values of independence, competence, stringency and transparency.*
		G47	*The particular use of a quite elaborate opinion survey, including a lot of discussions and face to face meetings with stakeholders, seems to be a very powerful tool to assess the impact of the information programme and is also a good way to obtain a performance indicator.*

APPENDIX VII – REFERENCE MATERIAL PROVIDED BY ASN

[1] COPESWASAP (6) Control of radioactivity in materials for recycling

[2] COPEWASAP (8) Regulatory Framework

[3] COPEWASAP (10) Control of foodstuffs

[4] COPEWASAP (12) control of discharges

[5] COPEWASAP (13) Environmental monitoring

[6] COPEWASAP (218) Radwaste management

[7] COPEWASAP (8) Control of chronic exposures

[8] ASN IRRS questionnaires

- *GS-R-1 (51) Module IV-VII*
- *GS-R-1 (105 Module I-III*
- *Irrs (3) Part III and IV Enforcement*
- *IRRS Part III and IV Regulatory body establishment and independence*
- *IRRS (4) Part III and IV International cooperation*
- *IRRS (5) Part III and IV Emergency Preparedness regulations*
- *IRRS (6) Part III and IV Medical exposure regulations*
- *IRRS (7) Part III and IV Notification and Source national register*
- *IRRS (9) Part III and IV Nuclear Medicine regulations*
- *IRRS (10) Part III and IV Diagnostic and interventional radiology regulations*
- *IRRS (11) Part III and IV Inspection*
- *IRRS (11) Part III and IV Radiotherapy regulations*
- *IRRS (11) Part III and IV Security of radioactive sources regulations*
- *IRRS (18) Part III and IV Safety and Security of radioactive sources*
- *IRRS (22) Part III and IV Legislation Sources*
- *IRRS (23) Part III and IV Radioactive source authorisations*
- *IRRS (30) Part III and IV Occupational radiation protection regulations*
- *IRRS (34) Part III and IV Regs basis of radiation Protection*

[9] ANI 01 – Management, V1

[10] AUT 01- Authorization, V0

[11] CTR 01 – Control and supervisions, V0

[12] GEN – General Organization, V1

[13] ORG 01 – Organization, V1

[14] ORG 02 – Delegation of signature, V1

[15] QUA 01 – Quality management, V0

[16] REG 01 – Regulations, V0

[17] REL 01 – Relations, V1

[18] Decree 2002-253 – Environment delegation

[19] Decree 2002-254 – IRSN

[20] Decree 2002-255 – DGSNR

[21] Decree 2002-257 – Minister of Health delegation

[22] Law 2006-686, 13.06.2006 – Transparency and Security in Nuclear Field Act.

[23] Decree 63-1228, 11 December 1963 concerning nuclear installations

[24] Decree 73-7278, 13 March 1973, 1973 High Council for Nuclear Safety

[25] Decree 95-540, 4 May 1995, water intake and discharge

[26] Law 61-842, 2 August 1962

[27] Law 61-842, 2 August 1962

[28] Order 10 August 1984, concerning Quality

[29] Order 10 November 1999, Primary and secondary pressurised systems

[30] Order 12 December 2005, PSSR

[31] Order 26 November 1999, water intake and discharge

[32] Order 31 December 1999 Modified, risk from NBI

[33] CSP L1333-1 a 20, Ionising radiation

[34] CSP L1337-1-1, 1337-4 to 9, penal provisions

[35] CSP R1333-1 to 93, public protection

[36] CT L231-7-1-R231-73 to 113, worker protection

[37] Joint convention fuel and radwaste management – France's answers

[38] Nuclear Safety convention – 3rd report

[39] 2004 0. Forewords

[40] 2004 0. Main topics

[41] 2004 0. Strategic Plan

[42] 2004 Appendix

[43] 2004 Annual Report

[44] 2005 0. ASN strategic plan

[45] 2005 0. Essential topics

[46] 2005 0. Forewords

[47] 2005 Annual Report

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

[1] ***No. GS-R-1*** *– Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*

[2] ***No. GS-R-2*** *– Preparedness and Response for a Nuclear or Radiological Emergency*

[3] ***No. GS-R-3*** *– The Management System for Facilities and Activities*

[4] ***No. GS-G-1.1*** *– Organization and Staffing of the Regulatory Body for Nuclear Facilities*

[5] ***No. GS-G-1.2*** *– Review and Assessment of Nuclear Facilities by the Regulatory Body*

[6] ***No. GS-G-1.4*** *– Documentation for Use in Regulatory Nuclear Facility*

[7] ***No. GS-R-2*** *– Preparedness and Response for Nuclear and Radiological Emergencies Requirements*

[8] ***No. WS-R-1*** *– Review and Assessment of Nuclear Facilities by the Regulatory Body*

[9] ***No. WS-R-2*** *– Predisposal Management of Radioactive Waste, including Decommissioning;*

[10] ***No. WS-R-3*** *– Remediation of Areas Contaminated by Past Activities and Accidents;*

[11] ***No. WS-R-4*** *– Geological Disposal of Radioactive Waste;*

[12] ***No. TS-R-1*** *– Regulations for the Safe Transport of Radioactive Material TS-R-1*

[13] ***No. Safety Series 115*** *– International Basic Safety Standards*

[14] ***No. NS-R-1/2*** *– Safety Requirements of Nuclear Power Plants: Operation and Design*

[15] ***No. NS-R-3*** *– Safety Requirements of Research Reactors*

[16] ***No. NS-R-4*** *– Safety Requirements of and Fuel Cycle Facilities*

APPENDIX IX – ASN ORGANIZATIONAL CHART